

EPA Registration No.  
89896-2  
Vol. 2

*checked*



**U.S. ENVIRONMENTAL PROTECTION  
AGENCY**

Office of Pesticide Programs  
Antimicrobials Division (7510C)  
1200 Pennsylvania Avenue NW  
Washington, D.C. 20460

EPA Reg.  
Number:  
89896-2

Date of Issuance:  
**MAY 23 2014**

Term of Issuance:  
**Unconditional**

Name of Pesticide Product:  
**CLEAN SMART**

**NOTICE OF PESTICIDE:**

☒ Registration  
☐ Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Seth DeGroot  
Simple Science Ltd  
530 N 3<sup>rd</sup> St., #310  
Minneapolis, MN 54401

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product (OPP Decision Number: D-485449) is unconditionally registered in accordance with FIFRA sec 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

Revise the EPA Registration Number to read, "EPA Reg. No. 89896-2.

Signature of Approving Official:

*[Signature]*  
Demson Fuller  
Product Manager Team 32  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Date:

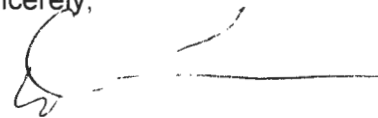
On page 1 of the current label, it was noted a website addition: [www.cleanSmartHome.com](http://www.cleanSmartHome.com) and [www.VetriCure.com](http://www.VetriCure.com) websites. Should you wish to retain a reference to the company's websites on your label, then please be aware that such a reference transforms the websites into labeling under the Federal Insecticide Fungicide and Rodenticide Act sec 2 (p) (2) and then the websites are subject to review by the Agency. If the websites content are false or misleading, the product would be misbranded and its sale or distribution unlawful to sell or distribute under FIFRA section 12(a)(1)(E). In addition, regardless of whether a websites are referenced on your product's label, claims made on the websites may not substantially differ from those claims approved through the registration process. Although EPA has not yet determined the extent to which it will routinely review company websites, if the Agency finds or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from claims approved through the registration process, the website may be referred to the EPA's Office of Enforcement and Compliance Assurance.

A stamped label with comments is enclosed for your records. Submit one (1) copy of your final printed labeling prior to release of this product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-8062 or by email at [fuller.demson@epa.gov](mailto:fuller.demson@epa.gov).

Sincerely,



Demson Fuller  
Product Manager 32  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Enclosures: (Stamped Label)

**Note: *Italicized text is information for the reader and is not part of the label.***

(Bracketed information is optional text.)

# CleanSmart

## Alternate Brand Name (ABN):

(CleanSmart All Purpose Cleaner & Disinfectant)  
 (CleanSmart Disinfectant ToGo)  
 (CleanSmart Disinfecting SmartSquirt)  
 (CleanSmart (Toy) Disinfecting Spray)  
 (VetriCure)  
 (VetriCure (Small) Pet Area Disinfectant)  
 (VetriCure Pet Area Disinfectant)  
 (CleanSmart Daily Disinfecting (Spray))  
 (VetriCure (Small) Pet Area (Disinfectant) (Sanitizer)  
 VetriCure Litterbox (Disinfectant) (Sanitizer)  
 VetriCure (Kennel) (Disinfectant) (Sanitizer)  
 VetriCure Reptile Area (Disinfectant) (Sanitizer)  
 CleanSmart Pacifier Sanitizer

CleanSmart Nursery and High Chair (Disinfecting) Cleaner  
 CleanSmart Toy Disinfectant  
 CleanSmart Daily Surface (Disinfecting) Cleaner  
 CleanSmart Disinfectant Spray (ToGo)  
 (CleanSmart Daily Disinfecting (Spray) ToGo)  
 (CleanSmart Daily Sanitizing (Spray))  
 (VetriCure Litterbox (Disinfectant Cleaner))  
 (VetriCure Kennel Disinfectant)  
 (VetriCure (Anywhere) (Everywhere) Hard Surface Disinfecting Spray)  
 (CleanSmart Daily Surface Cleaner Smart Spray)  
 (CleanSmart Hard Surface Sanitizing Spray)  
 CleanSmart (Anywhere) (Everywhere) Hard Surface Disinfecting Spray)  
 (CleanSmart (Anywhere) (Everywhere) Hard Surface Sanitizing Spray)

(A list of this product's ingredients is available) (at) (www.CleanSmartHome.com)(www.VetriCure.com)

Mfd. for Simple Science, LLC, (530 N 3<sup>rd</sup> St, # 310, Minneapolis, MN 55401)(\_\_\_\_\_)

(Happy, Healthy, Home, CleanSmart)(VetriCure) is a registered trademark of Simple Science, LLC.

(U.S. Patents pending) (\_\_\_\_\_).

EPA Reg. No. 89896-REPA Est. No. XXXXX-XX-X [see base of pack]

Net Contents: \_\_\_\_\_

(Ready to Use Broad Spectrum Disinfectant and Sanitizer for Hard Non-Porous Surfaces

For Commercial, Institutional, Cruise Ship and Household Use)

(CleanSmart - Pacifier Cleaner/Disinfectant/Sanitizing Spray)

(CleanSmart - Nursery Cleaner/Disinfectant/Sanitizing Spray)

(CleanSmart - Bottle Cleaner/Disinfectant/Sanitizing Spray)

(CleanSmart - Toy Cleaner/Disinfectant/Sanitizing Spray)

(Daily Kitchen Disinfectant Cleaner)

(Food-Contact Surfaces Disinfectant Cleaner)

(Bathroom Disinfectant Cleaner)

(Athlete's Foot Daily Surface Spray [Cleaner/Disinfectant])

(Sanitizing/Disinfecting Spray)

(Health Club Surface [Cleaner/Disinfectant/Sanitizing Spray])

(Neti Pot Sanitizing Cleaner)

(Kennel Disinfectant [Cleaner/Sanitizing Spray])

(Pet Area Cleaner [Disinfectant, Sanitizing Spray])

(Sports Gear Sanitizer [Disinfectant])

(CleanSmart/Simple Science Hospital Grade Disinfectant)

(CleanSmart/Simple Science Hospital Disinfectant)

(CleanSmart/Simple Science All Purpose Cleaner & Disinfectant)

(CleanSmart/Simple Science Multipurpose Cleaner & Disinfectant)

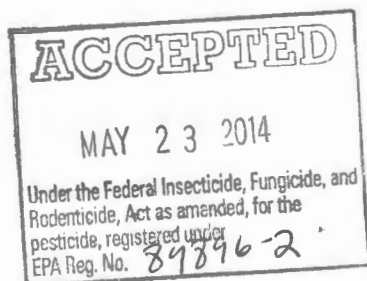
(CleanSmart/Simple Science Disinfectant for Neo-Natal Rooms)

(CleanSmart/Simple Science Disinfectant for Intensive Care Rooms)

(CleanSmart/Simple Science Disinfectant for Operating Rooms)

(Antibacterial Multisurface Cleaner)

(Sanitizing [Disinfecting] Glass Cleaner)



## Active Ingredient:

Hypochlorous Acid ..... 0.017%

Other Ingredients ..... 99.983%

Total ..... 100.0000%

## KEEP OUT OF REACH OF CHILDREN

(For further information) (Questions?) (Comments) (Call): \_\_\_\_\_

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### **DIRECTIONS FOR USE**

**It is a violation of Federal law to use this product in a manner inconsistent with its labeling.**

#### **SANITIZATION:**

##### **Hard, Non-Porous Non-food Contact Surfaces:**

###### **Spray**

(To kill 99.9% of bacteria on (all) non-food surfaces –or– sanitize (all) hard, non-porous non-food contact surfaces.) Spray (this product) on surface (until thoroughly wet). Let stand for 5 minutes. (If desired) wipe with paper towel or clean dish towel. (Air dry, no rinsing necessary.) For heavily soiled surfaces, (a) precleaning (step) is required.

**Organisms (list 1):** Escherichia coli (E. coli), Enterobacter aerogenes, Salmonella enterica (Salmonella), Staphylococcus aureus (Staph), Streptococcus pneumoniae (Strep), Vancomycin Resistant Enterococcus faecalis (VRE), Methicillin Resistant Staphylococcus aureus (MRSA)

##### **Hard, Non-Porous Food Contact Surfaces:**

###### **Spray**

(To kill 99.9% of bacteria on (all) food-contact surfaces –or– sanitize (all) food-contact surfaces.) Spray (this product) on surface. Let stand for 1 minute/60 seconds. (If desired) wipe with paper towel or clean dish towel. (Air dry, no rinsing necessary.) For heavily soiled surfaces, (a) precleaning (step) is required.

**Organisms (list 2):** Escherichia coli (E. coli), Salmonella typhi (Salmonella), Staphylococcus aureus (Staph)

#### **DISINFECTION:**

##### **Hard non-porous surfaces:**

###### **Spray**

(To kill 99.9% of germs on (all) hard, non-porous surfaces –or– disinfect (all) hard, non-porous surfaces.) Spray (this product) on surface (until thoroughly wet). Let stand for 10 minutes. (If desired) wipe with paper towel or clean dish towel. (Air dry, no rinsing necessary, even on food contact surfaces.) For heavily soiled surfaces, (a) precleaning (step) is required.

**Organisms (list 3):** Escherichia coli (E. coli), Salmonella enterica (Salmonella), Staphylococcus aureus (Staph), Streptococcus pyogenes (Strep), Vancomycin Resistant Enterococcus faecalis (VRE), Methicillin Resistant Staphylococcus aureus (MRSA), Pseudomonas aeruginosa (Pseudomonas), Listeria monocytogenes (Listeria), Herpes Simplex Virus Type 1 (Herpes), Herpes Simplex Virus Type 2 (Herpes), HIV Type 1 (HIV), Influenza A (H1N1), Rhinovirus Type 37 (Common Cold), Human Coronavirus, Respiratory Syncytial Virus (RSV), Trichophyton mentagrophytes (causes Athlete's Foot Fungus), when used as directed

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#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal, or cleaning of equipment.

**Pesticide Storage:** Store (this product) (CleanSmart) in its original sealed container at room temperature, away from direct sunlight and heat to avoid deterioration.

*(Note to reviewer: The following text is for residential/household containers.)*

**Pesticide Disposal and Container Handling:** Nonrefillable container. Do not use or refill this container. Wrap (container) and put in trash or offer for recycling if available.

*(Note to reviewer: The following text is for commercial/institutional containers.)*

**Pesticide Disposal:** Wastes from this use of this product may be disposed of on site or at an approved waste disposal facility.

**Container Handling:** Nonrefillable container. Do not use or refill this container. Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

#### PHYSICAL OR CHEMICAL HAZARDS

Do not use this product with other household or industrial products containing ammonia.

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#### GENERAL CLAIMS:

- |   |   |
|---|---|
| <ul style="list-style-type: none"> <li>• A (gentle) (mild) way to clean (list any use sites from Table 1 or 3)</li> <li>• (Gentle) (Mild) (cleaning) (cleaner)</li> <li>• A CleanSmart Home is a healthier home</li> <li>• A (healthier) (smarter) way to wipe up!</li> <li>• A new technology that can be used around your home ... on the surfaces touched most.</li> <li>• A revolutionary, pH balanced (neutralized) (disinfectant) (sanitizer)</li> <li>• All purpose (antibacterial) kitchen (cleaner) (spray) (sanitizer) (disinfectant)</li> <li>• Antibacterial (daily) kitchen (cleaner) (sanitizer) (spray) (disinfectant)</li> <li>• (Check out) (our) (website at) <a href="http://www.CleanSmartHome.com">www.CleanSmartHome.com</a> (for more information))</li> <li>• (Check out) (our) (website at) <a href="http://www.VetriCure.com">www.VetriCure.com</a> (for more information))</li> <li>• (Clean) (light) (airy) (mild) (fresh) fragrance -or- scent</li> <li>• Clear formula</li> <li>• (Anywhere) (Everywhere) hard surface sanitizer -or- sanitizing (spray)</li> <li>• (Anywhere) (Everywhere) hard surface disinfectant - or - disinfecting (spray)(Sanitize) (Disinfect) (Spray) fearlessly</li> <li>• Color safe</li> <li>• Will not whiten or bleach (surfaces) (or) (clothes)</li> <li>• (Contains) no (harsh) (harmful) (lingering) (cleaning) chemicals</li> <li>• (Controls) (stops) (prevents) the growth of odor-causing bacteria</li> <li>• (Daily) (everyday) (light duty) kitchen (cleaner) (sanitizer) (disinfectant) (spray)</li> <li>• (Easy) (and) (convenient) to use</li> <li>• (Easy) (fast acting) (convenient) way to sanitize</li> <li>• (Easy) (fast acting) (convenient) way to disinfect</li> <li>• (Fast acting) (and) (easy) for non-food surface sanitization (list organisms with 60 second contact time)</li> <li>• (Fast acting) (and) (easy) for food contact sanitization (list organisms)</li> <li>• (Economy) (institutional) (value) size -or- pack</li> <li>• (Economy) (value)</li> <li>• Eliminates buckets and rags for sanitizing</li> <li>• Eliminates need to test ppm level</li> <li>• Food-contact surface sanitizer</li> <li>• For (daily) (everyday) (gentle) (light-duty) (kitchen) cleaning -or- wiping</li> <li>• For (daily) (everyday) use</li> <li>• For a cleaner, fresher (bathroom) (kitchen) (home) (house) (pet areas), (kennel), (litter box)</li> <li>• For (sanitizing) (disinfecting) (food service) dining tables</li> <li>• Use without gloves</li> <li>• Gentle enough to clean (homes) (nurseries) (play rooms)</li> <li>• A (gentle) (mild) way to clean</li> <li>• Gentle Cleaning [Gently Cleans]</li> </ul> | <ul style="list-style-type: none"> <li>• Great for (daycare) (lavatory) (restaurant) (office) (school) use!</li> <li>• Great for (all around) (the) (house) (home) (kitchen)</li> <li>• Just spray (and) (wipe) (walk away) (no rinsing -or- wiping (is) necessary)</li> <li>• Kitchen (cleaner) (sanitizer) (spray) (disinfectant)</li> <li>• Latest in (sanitizing) (cleaning) (disinfection) technology</li> <li>• Leaves a streak-free shine</li> <li>• Leaves no (chemical) residue</li> <li>• Leaves surfaces shiny</li> <li>• Leaves your (kitchen) (home) (house) smelling clean</li> <li>• Leaves your kitchen (healthy)</li> <li>• Makes your job easier</li> <li>• No (harsh fumes) (accidental whitening)</li> <li>• No rinsing (necessary)</li> <li>• Non-abrasive formula</li> <li>• Cleaning and (sanitizing) (disinfecting)</li> <li>• Patent pending formulation</li> <li>• Perfect size for (bathrooms) (kitchens)</li> <li>• Perfect size for use all around the house</li> <li>• (Easy) (and) (Convenient) To Use</li> <li>• No rinse required (even on food contact surfaces)</li> <li>• For (hard, non-porous) surfaces that water won't harm</li> <li>• (Gentle) (Mild) (enough) to use on any washable hard, non-porous surface, including (list any surface from Table 1 or Table 2)</li> <li>• Sanitize - or - Disinfect without rinsing</li> <li>• The easy way to sanitize - or - disinfect food service operations (dining areas, countertops, checkouts)</li> <li>• The simple solution for a healthier home</li> <li>• The smell of clean</li> <li>• Try me</li> <li>• Use (daily) (everyday)</li> <li>• Use for a (fresh) (healthy) kitchen</li> <li>• Use for a healthier (kitchen) (home) (environment) (place)</li> <li>• For use around [home] [kitchen] [house] [bathroom]</li> <li>• (Use) for touch-up (kitchen) cleaning -or- wiping</li> <li>• (Use) for quick clean-ups</li> <li>• (Use) for wiping (bathroom) (kitchen) counters</li> <li>• Use throughout the (kitchen) (home) (house)</li> <li>• [Use] for [preschool] [daycare] [office] [assisted living] [senior care] kitchens</li> <li>• With a (light) touch -or- hint of (bleach) (fragrance)</li> <li>• (Worry free) (color safe) spray (that you can use around the house)!</li> <li>• For use all around the (kitchen) (home) (house)</li> <li>• For use on all (kitchen) (hard non-porous) surfaces</li> <li>• Breaks Down to Saline Solution</li> <li>• Tough on Germs</li> <li>• Fast (Acting)</li> </ul> |
|---|---|

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#### GENERAL CLAIMS:

- |  |  |
|--|--|
| <ul style="list-style-type: none"> <li>• Use around Pet water bowls</li> <li>• (Destroys) (Controls) (Eliminates) (Kills) germs on (animal) (pet) toys</li> <li>• (Destroys) (Controls) (Eliminates) (Kills) germs on (animal) (pet) chew toys</li> <li>• Spray on pet chew toys, no rinse required</li> <li>• (Destroys) (Controls) (Eliminates) (Kills) the germs found on chew toys</li> <li>• Stop the spread of germs, spray on animal chew toys</li> <li>• (Destroys) (Controls) (Eliminates) (Kills) germs, yet effective enough to use on pet (cages) (crates)</li> <li>• Use to keep (pet cages) (dog crates) (cat crates) (pet areas) healthy</li> <li>• Worry free use in (kennels) (litter box) (pet areas)</li> <li>• For healthier pet living areas</li> <li>• (Controls) (stops) (prevents) Pet odors from bacteria</li> <li>• While it's tough on bacteria, it's gentle on surfaces</li> <li>• (Anywhere) (Everywhere) Hard Surface Pet Sanitizer</li> <li>• No worries about pet licking after cleaning</li> <li>• Fragrance Free, won't irritate your dog's nose</li> <li>• No harsh fumes to irritate (pet) (dog) noses</li> <li>• Cleans up the pet mess and kills the germs on hard (non-porous) surfaces</li> <li>• Rinse-Free Spray; use (on) (around) (pacifiers) (highchairs) (and) (toys)</li> <li>• Breathe Easy: (Fragrance Free) (No Harsh Fumes) (No Harsh Chemicals)</li> <li>• Phenol Free</li> <li>• Alcohol Free</li> <li>• Food Contact Surface Sanitizer</li> <li>• (CleanSmart) (VetriCure) (makes) (has replicated) Hypochlorous using simple ingredients and really smart science.</li> <li>• Daily (Everyday) Surface Cleaner (&amp;) (Disinfectant)</li> <li>• (Baby) Toy (Cleaner) (&amp;) Disinfectant</li> <li>• (No Rinse)(.) (Just) (Spray &amp; Play)(.) (No Wipe)</li> <li>• Worry Free Use in Nursery</li> <li>• Worry Free Use On Toys</li> <li>• (3-in-1) Litter Box Sanitizer</li> </ul> | <ul style="list-style-type: none"> <li>• Happy. Healthy. Home. CleanSmart</li> <li>• (SmartSpray) (Daily) (Disinfecting) (All-Purpose) (Surface) Cleaner</li> <li>• (Destroys) (Controls) (Eliminates) (Kills) (Germs) (Bacteria) (&amp;) (Viruses) (Cold &amp; Flu) Clean &amp; Simple</li> <li>• (Destroys) (Controls) (Eliminates) (Kills)(99%) (99.9%) of (Germs) (Bacteria) (Viruses) (Bacteria &amp; Viruses) (Cold &amp; Flu) (RSV) (Strep) (Salmonella) (Listeria) (E. coli) (Athlete's Foot) (Trichophyton mentagrophytes)</li> <li>• Clean &amp; Simple. (No Harsh Chemicals) (Fragrance Free) (Simple Ingredients) (No Fragrance Added)</li> <li>• (Destroys) (Controls) (Eliminates) (Kills) (Respiratory Viruses), (Colds &amp; Flu), (RSV) &amp; (Strep)</li> <li>• Effective against Trichophyton mentagrophytes (cause of Athlete's Foot Fungus), when used as directed</li> <li>• Surface germ (ELIMINATOR) (KILLER) ({Mildew}, {Mold}, &amp; {Athlete's Foot})</li> <li>• (DESTROYS) (ELIMINATES) (food) pathogens (Listeria) (Salmonella) (E. coli)</li> <li>• (Never) harsh chemicals (,) (fumes) (or) (strong) (bad) (smelly) (odors).</li> <li>• Rinse FREE</li> <li>• No Rinse Required</li> <li>• Cleans the mess and kills the germs</li> <li>• Spray (anywhere) (everywhere) on hard surfaces (In Nursery)</li> <li>• Kills odor causing bacteria (Pet)</li> <li>• Controls Mildew mold and Athletes foot</li> <li>• Eliminate Poop (fecal matter) Germs: E. coli &amp; Salmonella</li> <li>• VetriCure is the pet area (disinfecting) (disinfectant) (clearer) that kills 99.9% of germs, and is gentle enough (is gentle enough for pet living areas)</li> <li>• Orthotics</li> <li>• (Innovative) (Breakthrough) (Clean &amp; Simple) Germ Killer</li> <li>• Clean, Simple Ingredients plus (Remarkable) (Innovative) (Breakthrough) (Patented) Technology = (CleanSmart) (VetriCure)</li> <li>• Kills (the Common) (Cold*) (&amp;) (Flu*)</li> <li>• For use in (newborn) nurseries</li> <li>• For use in neonatal nurseries</li> <li>• No Dyes</li> <li>• (Non-porous, Hard Surface) Kennel Disinfectant</li> <li>• No Bleach (Bleach Free)</li> <li>• (Disinfecting) (Disinfectant) Spray</li> </ul> |
|--|--|

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### SANITIZING CLAIMS:

- A(n) (fast acting) (and) easy way to (kill) (eliminate) (destroy) (remove) 99.9% of (bacteria) (germs) in your (bathroom) (home) (house) (kitchen)
- Antibacterial
- Can help reduce the risk of cross-contamination on (hard, non-porous) surfaces
- Can reduce the spread of illness-causing (kitchen) bacteria (on hard, nonporous surfaces)
- Eliminates food odors like garlic and onion left behind on kitchen surfaces after cooking
- Eliminates odors caused by bacteria
- Food (contact) (preparation) (hard, non-porous) surface (sanitizer)
- Food serving area sanitizer
- (Gently) (lightly) cleans and (kills) (eliminates) (destroys) (removes) 99.9% of (kitchen) bacteria
- (Gently) (lightly) cleans and removes 99.9% of (kitchen) bacteria
- Kills 99.9% of bacteria Salmonella and E. coli (on) (food contact surfaces) (food preparation surfaces) (food serving areas)
- Kills 99.9% of bacteria in 5 minutes
- Kills 99.9% of bacteria\*\* on food contact surfaces in 1 minute
- Kills 99.9% of bacteria like Salmonella and E. coli (on) (food contact surfaces) (food preparation surfaces) (food serving areas)
- Kills 99.9% of bacteria\*\* (on) (food contact surfaces) (food preparation surfaces) (food serving areas)
- Kills 99.9% of bacteria\*\* that can cause foodborne illness (food poisoning)
- Kills 99.9% of bacteria\*\* (on) (food contact surfaces) (food preparation surfaces) (food serving areas)
- Kills 99.9% of household bacteria<sup>+</sup>
- Kills 99.9% of the bacteria<sup>+</sup> commonly found in kitchens and bathrooms
- Kills 99.9% of the bacteria<sup>+</sup> you can't see
- (Kills) (eliminates) (destroys) (removes) 99.9% of bacteria<sup>+</sup> (all) around your (bathroom) (kitchen) (home) (house)
- (Kills) (eliminates) (destroys) (removes) 99.9% of bacteria<sup>+</sup> (all) around your (bathroom) (kitchen) (home) (house)
- (Kills) (eliminates) (destroys) (removes) 99.9% of bacteria, including E. coli and Salmonella
- (Kills) (eliminates) (destroys) (removes) 99.9% of bacteria, like Salmonella, Strep, Staph and E. coli (on hard, non-porous )(surfaces]

- (Kills) (eliminates) (destroys) (removes) 99.9% of bacteria on commonly touched (hard, non-porous) surfaces that can be transfer points for bacteria (such as doorknobs, telephones, keyboards, and light switches)
- (Kills) (eliminates) (destroys) (removes) 99.9% of bacteria on: (list any surface from Table 1 or Table 2)
- (Kills) (eliminates) (destroys) (removes) 99.9% of bacteria<sup>+</sup> (on hard, nonporous surfaces)
- (Kills) (eliminates) (destroys) (removes) 99.9% of bacteria on hard, nonporous surfaces (Kills) (eliminates) (destroys) (removes) 99.9% of bacteria on hard, nonporous surfaces (all) around the (bathroom) (kitchen) (home) (house)
- (Kills) (eliminates) (destroys) (removes) 99.9% of bacteria<sup>+</sup>
- (Kills) (eliminates) (destroys) (removes) 99.9% of bacteria<sup>+</sup>
- (Kills) (eliminates) (destroys) (removes) 99.9% of common household bacteria
- Kills odor causing bacteria
- Leaves household surfaces sanitized
- Sanitizes
- Sanitizes food-contact (preparation) surfaces (without rinsing)
- Sanitizes food serving areas (without rinsing)
- Eliminates Odors
- Eliminates Odors & Freshens the Air

#### << Sanitization Organism List >>

Hard, non-porous non-food contact surfaces:

\* Escherichia coli (E. coli), Enterobacter aerogenes, Salmonella enterica (Salmonella), Staphylococcus aureus (Staph), Streptococcus pneumoniae (Strep), Vancomycin Resistant Enterococcus faecalis (VRE), Methicillin Resistant Staphylococcus aureus (MRSA)

Hard, non-porous food contact surfaces:

\*\* Escherichia coli (E. coli), Salmonella typhi (Salmonella), Staphylococcus aureus (Staph)

Hard, non-porous surfaces:

<sup>+</sup> Escherichia coli (E. coli), Enterobacter aerogenes, Salmonella enterica (Salmonella), Salmonella typhi (Salmonella), Staphylococcus aureus (Staph), Streptococcus pneumoniae (Strep), Vancomycin Resistant Enterococcus faecalis (VRE), Methicillin Resistant Staphylococcus aureus (MRSA)

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(Bracketed information is optional text.)

#### DISINFECTION CLAIMS:

- Kills {Insert microorganisms in list 3; found below the sanitization and disinfection instructions}
- Kills 99.9% of (bacteria) (germs\*\*)
- Kills 99.9% of (bacteria) (germs\*\*) (such as) (E. coli) (Salmonella) (and) (MRSA) (Methicillin Resistant Staphylococcus aureus)
- Kills 99.9% of bacteria\*
- Kills 99.9% of germs\*\*
- Kills bacteria\*
- Kills bacteria commonly found in the (kitchen) (and) (bathroom)\*
- Kills germs\*\*
- Cleans while it kills germs\*\*
- Kills household bacteria\*
- Kills (household) bacteria\* (in 10 minutes) (commonly found in kitchens) (on hard, non-porous surfaces)
- Kills (household) bacteria\* )
- Kills kitchen and bathroom bacteria\*
- Kills more than 99.9% of bacteria and viruses\*\*
- Kills odor-causing bacteria\*
- Kills odor-causing (household) bacteria\*
- (Kills) (Destroys) (Eliminates) germs\*\*
- (Kills) (Eliminates) odor-causing bacteria\* in the (kitchen) (bathroom) (restroom) (all around the house)
- Kills (kitchen) (bathroom) (household) germs\*\*
- Kills bacteria\* commonly found in kitchens (in 10 minutes)
- Kills bacteria\* and viruses\*\* on hard, non-porous (kitchen) (bathroom) (restroom) (household) surfaces in 10 minutes
- Kills viruses<sup>+</sup>
- Proven to kill 99.9% of (bacteria\*) (germs\*\*) (such as) (E. coli) (Salmonella) (and) (MRSA) (Methicillin resistant Staphylococcus aureus)
- Proven to kill 99.9% of bacteria (such as E. coli, Salmonella and MRSA)
- Removes (bacteria) (germs\*\*)
- Takes care of (bacteria) (germs\*\*)
- (Kills) (eliminates) (destroys) 99.9% of bacteria on hard, nonporous surfaces in Pet living areas
- (Kills) (eliminates) (destroys) 99.9% of germs on hard, nonporous surfaces in Pet living areas
- Eliminates Odors
- Eliminates Odors & Freshens the Air

\* Kills (99.9% of) {Insert Organism} (on hard, non-porous surfaces) (in 10 minutes)

\*\* Kills (99.9% of) {Insert Organism} (on hard, non-porous surfaces) (in 10 minutes) (99.9% of) {insert Organism} (on hard, non-porous surfaces) (in 10 minutes)

#### << Disinfection Organism List >>

\* Escherichia coli (E. coli), Salmonella enterica (Salmonella), Staphylococcus aureus (Staph), Streptococcus pyogenes (Strep), Vancomycin Resistant Enterococcus faecalis (VRE), Methicillin Resistant Staphylococcus aureus (MRSA), Pseudomonas aeruginosa (Pseudomonas), Listeria monocytogenes (Listeria)

\*\* Escherichia coli (E. coli), Salmonella enterica (Salmonella), Staphylococcus aureus (Staph), Streptococcus pyogenes (Strep), Vancomycin Resistant Enterococcus faecalis (VRE), Methicillin Resistant Staphylococcus aureus (MRSA), Pseudomonas aeruginosa (Pseudomonas), Listeria monocytogenes (Listeria), Herpes Simplex Virus Type 1 (Herpes), Herpes Simplex Virus Type 2 (Herpes), HIV Type 1 (HIV), Influenza A (H1N1), Rhinovirus Type 37 (Common Cold), Human Coronavirus, Respiratory Syncytial Virus (RSV), effective against Trichophyton mentagrophytes (cause of Athlete's Foot Fungus), when used as directed

<sup>+</sup> Herpes Simplex Virus Type 1 (Herpes), Herpes Simplex Virus Type 2 (Herpes), HIV Type 1 (HIV), Influenza A (H1N1), Rhinovirus Type 37 (Common Cold), Human Coronavirus, Respiratory Syncytial Virus (RSV)

**Note: *Italicized text is information for the reader and is not part of the label.***

(Bracketed information is optional text.)

USE SITES (Table 1):			
<ul style="list-style-type: none"> <li>• Around Toilet Areas</li> <li>• (Around) Toilets</li> <li>• Automobiles</li> <li>• Animal Equipment</li> <li>• Baby Bottles</li> <li>• Baby Toys</li> <li>• (Bath)tubs</li> <li>• Bathroom (counter) tops</li> <li>• Bathroom (surfaces)</li> <li>• Beverage bars</li> <li>• Blinds</li> <li>• Boat interiors</li> <li>• Booster chairs</li> <li>• Breast pump parts</li> <li>• Breast pumps</li> <li>• Cabinet Handles</li> <li>• Cabinets</li> <li>• Can openers</li> <li>• Cars</li> <li>• Children's (Kid's) (Wading) pool</li> <li>• Children's (Kid's) Table</li> <li>• (Computer) Keyboards</li> <li>• Counter(s) -or- Countertop(s)</li> <li>• Car interiors</li> <li>• Cupboards</li> <li>• Dairy cases</li> <li>• (Diaper) Changing Tables</li> <li>• Diaper Pails</li> <li>• Dining Room Tables</li> <li>• Dish Racks</li> <li>• Dishwashers</li> <li>• New born Nurseries</li> <li>• Neonatal Nurseries</li> </ul>	<ul style="list-style-type: none"> <li>• Door Handles</li> <li>• Doorknobs</li> <li>• Doors</li> <li>• Drainboards</li> <li>• Dryers</li> <li>• (Empty) Clothes Hampers</li> <li>• (Empty) Garbage Cans</li> <li>• Faucets</li> <li>• Floors</li> <li>• Food Cases</li> <li>• Food Contact Surfaces-hard non-porous</li> <li>• Food Preparation (surfaces) (areas)</li> <li>• Food serving areas</li> <li>• Food trays</li> <li>• Freezers</li> <li>• Grills</li> <li>• Grocery Carts</li> <li>• (Grocery) Checkout Areas</li> <li>• Handrails</li> <li>• High Chair Trays</li> <li>• High Chairs</li> <li>• Inside Dishwasher(s) (interiors)(and)(exteriors)</li> <li>• (Inside) Freezer(s) (interiors) (and) (exteriors)</li> <li>• (Inside) Microwave(s) (interiors) (and) (exteriors)</li> <li>• (Inside) Refrigerator(s) (interiors) (and)</li> </ul>	<ul style="list-style-type: none"> <li>• Kid's (Children's) Playroom (Toys)</li> <li>• (Kitchen) Appliances</li> <li>• (Kitchen) (Bathroom) Sinks</li> <li>• Kitchen (Counter)tops</li> <li>• (Kitchen) (dining room) Tables</li> <li>• Kitchen surfaces</li> <li>• Kitchen tools</li> <li>• Knives</li> <li>• Laundry Rooms</li> <li>• Light Switches</li> <li>• Litter box</li> <li>• Lunch Pails</li> <li>• Medicine Dropper</li> <li>• Mouthguard</li> <li>• Neti Pots</li> <li>• Oven doors</li> <li>• Ovens</li> <li>• Pacifiers</li> <li>• Pet Bowl(s) (Areas)</li> <li>• Pet Feeding Dishes</li> <li>• Pet Cages</li> <li>• Pet Toys</li> <li>• Piano Keys</li> <li>• Plastic Cutting Boards*</li> <li>• Plastic Patio Furniture</li> <li>• Playpens</li> <li>• Potty-Chair(s) (Seats)</li> <li>• Preschools</li> <li>• Range hoods</li> <li>• Range tops</li> <li>• Recycling Bins</li> <li>• Day Cares</li> <li>• Nursing Homes</li> <li>• Assisted Living</li> <li>• Orthotics</li> <li>• Hard surface yoga mats</li> </ul>	<ul style="list-style-type: none"> <li>• Refrigerators</li> <li>• Restrooms</li> <li>• (Salad bar) Sneeze Guards</li> <li>• Shower (Faucets) (Doors) (Handles) (Fixtures) (Walls) (Floors)</li> <li>• Sink (Faucets) (fixtures) (Handles)</li> <li>• Snack counters</li> <li>• Soap Dispensers</li> <li>• Storage Areas</li> <li>• Stovetops</li> <li>• Steering wheel</li> <li>• Thermos</li> <li>• Toasters</li> <li>• Toilet [(Flushing) (handles) (seats) (surfaces) (exteriors)]</li> <li>• Tongs</li> <li>• Towel (tissue) dispensers</li> <li>• Under sinks</li> <li>• Vanities</li> <li>• Vanity Tables</li> <li>• (Vinyl) Shower Curtains</li> <li>• Walls</li> <li>• Washing Machines</li> <li>• Windowsill</li> <li>• Baby swings</li> <li>• Phones</li> <li>• Keys</li> <li>• Cribs</li> <li>• Kennels</li> <li>• Garbage Can</li> <li>• Waste basket</li> <li>• Pee mats</li> <li>• Offices</li> </ul>

USE SURFACES (Table 2):			
<ul style="list-style-type: none"> <li>• Ceramic -and/or- Glazed Tile</li> <li>• Chrome</li> <li>• Corian</li> </ul>	<ul style="list-style-type: none"> <li>• Formica</li> <li>• Glass</li> <li>• Linoleum</li> <li>• Metal</li> </ul>	<ul style="list-style-type: none"> <li>• Non-Porous Plastic</li> <li>• Glazed Porcelain</li> <li>• Sealed Granite</li> <li>• Sealed Marble</li> </ul>	<ul style="list-style-type: none"> <li>• Stainless Steel</li> <li>• Vinyl</li> <li>• Finished -and/or- Painted Wood</li> </ul>

**Note: *Italicized text is information for the reader and is not part of the label.***

(Bracketed information is optional text.)

Organism Table for Sanitizing and Disinfecting Applications

<b>Bacteria: Broad-Spectrum &amp; Hospital</b>	<b>Contact Time</b>
<i>Staphylococcus aureus</i> (ATCC 6538)	10 minutes
<i>Salmonella enterica</i> (ATCC 10708)	10 minutes
<i>Pseudomonas aeruginosa</i> (ATCC 15442)	10 minutes
<i>Streptococcus pyogenes</i> (ATCC 19615)	10 minutes
<i>Enterococcus faecalis</i> (VRE) (ATCC 51575)	10 minutes
Methicillin Resistant <i>Staphylococcus aureus</i> (MRSA) (ATCC 33592)	10 minutes
<i>Listeria monocytogenes</i> (ATCC 19117)	10 minutes
<i>Escherichia coli</i> (ATCC 11229)	10 minutes
<b>Viruses:</b>	10 minutes
Herpes Simplex Virus Type 1 (ATCC VR-733)	10 minutes
Herpes Simplex Virus Type 2 (ATCC VR-734)	10 minutes
Human Immunodeficiency Virus (HIV) Type 1, Strain HTLV-III <sub>B</sub>	10 minutes
Influenza A (H1N1) (ATCC VR-1469)	10 minutes
Rhinovirus Type 37 (ATCC VR-1147, Strain 151-1)	10 minutes
Human Coronavirus (ATCC VR-740, Strain 229E)	10 minutes
Respiratory Syncytial Virus (RSV) (ATCC VR-26)	10 minutes
<b>Fungi:</b>	
<i>Trichophyton mentagrophytes</i> (ATCC 9533)	10 minutes
<b>Non-food Contact:</b>	
<i>Staphylococcus aureus</i> (ATCC 6538)	5 minutes
<i>Enterobacter aerogenes</i> (ATCC 13048)	5 minutes
<i>Escherichia coli</i> (ATCC 11229)	30 seconds
<i>Streptococcus pneumonia</i> (ATCC 6305)	30 seconds
<i>Salmonella enterica</i> (ATCC 10708)	30 seconds
Methicillin Resistant <i>Staphylococcus aureus</i> (MRSA) (ATCC 33592)	30 seconds
Vancomycin Resistant <i>Enterococcus faecalis</i> (VRE) (ATCC 51575)	30 seconds
<b>Food Contact:</b>	
<i>Escherichia coli</i> (ATCC 11229)	60 seconds
<i>Staphylococcus aureus</i> (ATCC 6538)	60 seconds
<i>Salmonella enterica</i> (ATCC 10708)	60 seconds

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(Bracketed information is optional text.)

#### **MEDICAL APPLICATIONS:**

**For Pre-cleaning Instruments, Equipment and Surfaces Prior to Disinfection:** Apply directly to the surface. Allow to remain wet for 30 seconds. Wipe surface using a paper or cloth towel to dry. Discard towel.

**For Disinfecting Non-critical Instruments and Equipment Surfaces:** Thoroughly pre-clean surfaces prior to disinfection. Apply directly to pre-cleaned surfaces, thoroughly wetting area to be disinfected. Allow the surface to be wet for 10 minutes at room temperature. Wipe surface using a paper or cloth towel to dry. Discard towel.

**For Use As a Pre-cleaning Spray:** Place instruments into suitable container. Spray disinfectant solution onto instruments so as to thoroughly wet all surfaces. Allow to remain wet for 30 seconds. Remove the instruments. Follow with appropriate cleaning and disinfection process by following directions for that product. When the solution becomes diluted or visibly soiled, change solution. The product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contact intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical devices prior to sterilization of high level disinfection.

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(Bracketed information is optional text.)

### MEDICAL APPLICATIONS (cont):

Multipurpose broad spectrum disinfectant for use in healthcare and other areas where control of cross contamination on hard non-porous surfaces is required [Pandemic 2009 H1N1 Influenza A Virus] [MRSA]. May be used for instrument pre cleaning and disinfection of non critical instruments. May be used on hard nonporous surfaces such as [*insert surface from Medical Hard Nonporous Surface Materials list*]

**Medical Hard Nonporous Surface Sites Table 3:**

acute care facilities	high touch surfaces	(hospital) Kitchens
Autoclaves	[hospital or patient] bed railings or linings or frames	hospitals
bed pans	[inner] [inside of] drawers	intensive care units
bed railing	IV poles	Isolation areas
behind and under wash basins	mammography equipment	Labs or Laboratories
blood glucose monitors	patient chairs	(medical) clinics
cabinet handles	phone cradle	Transport vehicles
pipes	Ultrasound transducers	(rv) Remote(s) (controls)
[plastic or vinyl] mattress covers	IV Stands	(Mayo) (instrument) stands
desktops	reception counters or desks or areas	
[exam or examination] tables	shower fixtures	
exterior surfaces of air vent exteriors	stretchers	
external [Medical] equipment surfaces	wheelchairs	
external surfaces of dialysis machines	external surfaces of respiratory equipment	
orthotics	hard nonporous hospital surfaces	
hard nonporous medical surfaces	external surfaces of ultrasound transducers & probes	
ambulance or transport vehicles	medical facilities	
anesthesia rooms or areas	medical or physicians or doctors' offices	
[assisted living or full care] nursing homes	neonatal intensive care units [(NICU)]	
[bed] head [foot] board	newborn or neonatal nurseries	
blood banks	nurse call [device] [button] [and cord]	
nursing or nurses stations	nursing or rest homes	
[blood] [plasma] [semen] donation centers	operating room[s] or OR[s]	
bp monitors	ophthalmic offices	
carts	orthopedic[s] [clinics]	
CAT labs or laboratories	outpatient clinics	
central service	outpatient surgical centers	
central service areas	patient care areas	
chemotherapy hoods	patient restrooms	
critical care units or CCUs	patient rooms	
[external] or [exterior of] dialysis machines	[pediatric] exam or examination rooms or areas	
emergency rooms or ERs	pharmacies	
exam or examination rooms	physical therapy rooms or areas	
[eye] surgical centers	physician offices	
footboards	radiology or x ray rooms or areas	
glucometer or blood glucose monitors	recovery rooms	
headboards	rehabilitation	
health care settings or facilities	respiratory therapy rooms or areas	
home health care	sill[s] ledge[s]	
hospices	surgery rooms or operating rooms or ORs	

**Note: *Italicized text is information for the reader and is not part of the label.***

(Bracketed information is optional text.)

#### GENERAL MEDICAL CLAIMS

- Acute care facilities[Cleans] [and] Disinfects [& Deodorizes] Fight[s] and/or Kill[s] and/or Effective against (*insert organism from lists 1, 2 and 3; found below the sanitization and disinfection instructions*) [in (*insert appropriate contact time for respective organism*)]
- Kills [99.9%] of bacteria, viruses & fungi in 10 min[utes] on Hard, Nonporous Surfaces. Kills Pandemic 2009 H1N1 Influenza A Virus
- Kills MRSA
- Ready to use Disinfectant
- Kills cold\* and flu viruses\*  
\*Influenza A (H1N1) and Rhinovirus Type 37
- Meets AOAC germicidal spray standards for Hospital Grade Disinfectants
- Meets OSHA blood borne pathogen standards
- Bactericidal
- Disinfectant
- Effective against [Influenza A H1N1] [H1N1] [MRSA] [and] [(*insert organism list from Organism List*)]
- Effective against Avian Influenza A and H1N1 [Pandemic] [Influenza A virus]
- Effective against MRSA
- Fungicidal\*\*  
\*\*Trichophyton mentagrophytes
- Kills Pandemic 2009 H1N1 Influenza A Virus [(formerly called swine flu)]
- [**Product Name**] [This Product] has demonstrated effectiveness against Staphylococcus aureus and is expected to inactivate Staphylococcus aureus, including the drug resistant superbug Methicillin-resistant Staphylococcus aureus (MRSA)
- Virucidal\*\*\*  
\*\*\*Herpes Simplex Virus Type 1 (Herpes), Herpes Simplex Virus Type 2 (Herpes), HIV Type 1 (HIV), Influenza A (H1N1), Rhinovirus Type 37 (Common Cold), Human Coronavirus, Respiratory Syncytial Virus (RSV)

#### VETERINARY / ANIMAL FACILITIES APPLICATIONS:

CleanSmart is a disinfectant that is especially useful in veterinary practices, animal care, animal laboratory, zoos, and pet shops.

To clean and disinfect hard, nonporous surface, remove all litter, droppings and manure from floors, walls and surfaces or facilities occupied or traversed by animals. Saturate surfaces with (CleanSmart) for a period of 10 minutes. Allow equipment and housing to completely dry after use.

**Liem, David**

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**From:** Wormell, Lance  
**Sent:** Friday, May 16, 2014 4:11 PM  
**To:** Fuller, Demson; Liem, David  
**Cc:** Hardy, Jacqueline  
**Subject:** Re: Follow Up/Conference Call with Exponent - 5/16

Thank you for continuing to work this. Please draft the two-day letter and work with RD and we can discuss on Monday.

---

**From:** Fuller, Demson  
**Sent:** Friday, May 16, 2014 3:18:39 PM  
**To:** Wormell, Lance; Liem, David  
**Cc:** Hardy, Jacqueline  
**Subject:** Follow Up/Conference Call with Exponent - 5/16

Hi Lance and David,

I had a conference call with the applicant (Simple Science) and their agent (Exponent) this morning in regards to labeling. Among other things, there was some progress:

- They can have the terms "anywhere" and "everywhere" if they qualify it with "hard surface"
- Terms such as "kids, babies, family, cats, dogs, and pets will be removed.
- The claim "color safe" is acceptable.
- The term "worry free" is acceptable, when used in the context of a use site or object (e.g., nursery, playroom, table, toy...)
- The term "gentle and mild" are acceptable when used in the context of a use site or object (see above bullet)
- The claim Fragrance Free – won't irritate your dog's or pet's nose is acceptable
- The term "sensitive" must be removed
- The claims "phenol, alcohol and bleach free are acceptable
- The claim "hypochlorous acid is produced by (our own bodies, mammals, animals, to fight germs, infection, viruses, bacteria" must be removed
- The claim "inspired by what our own bodies produce to fight infection" ...must be removed.
- The claim and use "prosthetics" must be removed.
- The claim "a cause of ringworm" must be removed. I spoke with efficacy. Data to prove that the product is effective against the test species *Trichophyton rubrum* must be submitted to support that claim.
- The term "using simple ingredients" and "really smart science" is acceptable.

While there was progress regarding some of the changes, there are still some sticking points in regards to moving forward with a stamped label at this time. A couple of issues remain:

- The term "Pure". They did not want to remove the claim because they feel as if the product has components (such as [REDACTED]) that justify that the product has natural components that are clear of impurities. After speaking with Jacque, Mark Perry and Karen Hill, we all agreed that it would not fly. I want to chat with RD (Venus Eagle) on Monday to get her thoughts. She and I were a part of the OPP Distributor Labeling committee and I have seen their division reject claims often. I want to get a firm justification when we go back to the company to discuss.
- The label – They submitted a revised version on 5/14. Based on the comments that we sent to them on 5/6, they deleted some of what we told them to remove but "added" a number of claims that were not part of the

original label. Because they may add new claims that We need to make sure that they have removed the claims that they are supposed to take off.

I told Exponent that while we will try to work with them to address these issues and hopefully get a reg notice and stamped label to them by Monday, but I am pessimistic that it will be likely. I propose that we draft a PRIA close out-two day letter, without the stamped label and send it to the company on Monday afternoon. David, could you take the lead on this? Attached is a template of the letter. In addition David, I will leave you a copy of the marked up label I had from today's conference call on your chair.

Let me know your thoughts.

Demson

*Demson Fuller*

Product Manager, Team 32  
US Environmental Protection Agency  
Office of Pesticide Programs  
Antimicrobials Division  
Regulatory Management Branch II  
(703)-308-8062

*updated -  
final*

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

ENVIRONMENTAL PROTECTION

OFFICE OF  
CHEMICAL SAFETY  
AND POLLUTION  
PREVENTION

Revised May 7, 2014  
April 22, 2014

**MEMORANDUM**

**SUBJECT:** Efficacy Review for Clean Smart;  
EPA Reg. No. 89896-E;  
DP Barcode: D417075

**FROM:** Karen M. Hill, Ph.D. *K Hill 5/7/14*  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510P)

**THRU:** Mark Perry *MJP*  
Team Leader  
Product Science Branch  
Antimicrobials Division (7510P)

**TO:** Demson Fuller RM32/ David Liem  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

**APPLICANT:** Simple Science Limited  
530 N 3<sup>rd</sup> St. #310  
Minneapolis, MN. 55401

**Formulation from the Label:**

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Hypochlorous Acid.....	0.017%
<u>Inert Ingredients</u> .....	99.983%
<u>Total</u> .....	100.000%

## **I. BACKGROUND:**

The product, CleanSmart (EPA Reg. No. 89896-E), is submitting efficacy studies in support of registration for a product as a new-end use as a disinfectant and sanitizer for use on hard non-porous surfaces in household, commercial, and institutional environments. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant's representative to EPA dated November 26, 2013, twenty one (21) studies (MRID 492603-05 thru MRID 492603-25), EPA Form 8570-4 (CSF), and Statement of No Data Confidentiality Claims within all studies.

## **II. USE DIRECTIONS:**

The proposed label direction for disinfection on hard non-porous environmental surfaces is given below:

(To kill 99.9% of germs on (all) hard, non-porous –or- disinfect (all) hard, non-porous surfaces.) Spray (this product) on surface (until thoroughly wet). Let stand for 10 minutes. (If desired) wipe with paper towel or clean dish towel. (Air dry. No rinsing necessary, even on food contact surfaces.) For heavily soiled surfaces, (a) precleaning (step) is required.

The proposed label direction for sanitization on hard non-porous environmental surfaces is given below:

(To kill 99.9% of germs on (all) hard, non-porous –or- disinfect (all) hard, non-porous surfaces.) Spray (this product) on surface (until thoroughly wet). Let stand for 5 minutes. (If desired) wipe with paper towel or clean dish towel. (Air dry. No rinsing necessary.) For heavily soiled surfaces, (a) precleaning (step) is required.

(To kill 99.9% of germs on (all) hard, non-porous –or- disinfect (all) hard, non-porous surfaces.) Spray (this product) on surface (until thoroughly wet). Let stand for 1 minute/60 seconds. (If desired) wipe with paper towel or clean dish towel. (Air dry. No rinsing necessary.) For heavily soiled surfaces, (a) precleaning (step) is required.

## **III. AGENCY STANDARDS FOR PROPOSED CLAIMS:**

### Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments:

The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products), or the AOAC Hard Surface Carrier Test. The tests require that sixty carriers must be tested with each of 3 samples, representing 3 different batches, one of which is at least 60 days old or all tested batches at or below the active ingredient(s) lower certified limit(s), against a mean log density of at least 6 for

*Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). To support products labeled as “disinfectants”, killing on 59 out of 60 carriers for germicidal spray testing is required to provide effectiveness at the 95% confidence level. To pass performance requirements when using AOAC Hard Surface Carrier Test, tests must result in killing in 58 out of each set of 60 carriers for *Staphylococcus aureus* ATCC 6538; 57 out of each set of 60 carriers for *Pseudomonas aeruginosa* ATCC 15442 within ten minutes. For AOAC Use-Dilution testing, testing for each lot should be conducted on a different day. Thus, a total of three tests for *S. aureus* and three tests for *P. aeruginosa* are necessary. Sixty carriers are required per test, without contamination in the subculture media. The performance standard for *S. aureus* is 0-3 positive carriers out of sixty. The performance standard for *P. aeruginosa* is 0-6 positive carriers out of sixty. To be deemed an effective product, the product must pass all tests for both microbes.

#### Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria):

Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as “disinfectants” for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required.

#### Sanitizers (For Non-Food Contact Surfaces)

The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as “one-step sanitizers” should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

#### Sanitizing Rinses (For Previously Cleaned Food Contact Surfaces):

Sanitizing rinses may be formulated with iodophors, mixed halides, or chlorine-bearing chemicals, among other active ingredients. The effectiveness of halide sanitizing rinses for previously cleaned food contact surfaces must be substantiated by data derived from the AOAC International Chlorine (Available) in Disinfectants Germicidal Equivalent Concentration test. Data from one test on each of 3 product samples, representing 3 different batches, one of which is at least 60 days old against *Salmonella enterica* (ATCC 6539) or *Staphylococcus aureus* (ATCC 6538). Performance standard: Test results must show product concentrations equivalent in activity to 50, 100, and 200 ppm of available chlorine.

There are cases where an applicant requests to make claims of effectiveness against additional microorganisms for a product already registered as a sanitizing rinse for previously cleaned food contact surfaces. Confirmatory test standards would apply. Thus, 2 product samples, representing 2 different batches, must be tested against each

additional microorganism. It would consider and evaluate data generated from the AOAC International Chlorine (Available) in Disinfectants Germicidal Equivalent Concentration test. One sample should be evaluated for efficacy against *Salmonella enterica* (ATCC 6539). Performance standard: Test results must show product concentrations equivalent in activity to 50, 100, and 200 ppm of available chlorine. The reference standard is sodium hypochlorite.

Virucides:

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least  $10^4$  from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. If the product is intended to be represented as a one-step virucidal, an appropriate organic soil (i.e. - 5 percent blood serum) should be included with the viral inoculum.

Supplemental Claims:

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

**IV. COMMENTS ON THE SUBMITTED EFFICACY STUDY:**

**The product's Certificate of Analysis which incorporated each tested lot was provided. Testing of the active ingredients concentration was performed by Case Laboratories, Inc. at 622 Route Ten Whippany, NJ 07901. The results of the testing are given below.**

<b>Lot</b>	<b>Hypochlorous Acid Active Ingredient Concentration</b>
CS001	99.5 ppm
CS002	100 ppm
CS003	102 ppm

**All of the batches tested were at or below the lower certified limit of the active ingredient hypochlorous acid.**

**1. MRID 492603-05, "AOAC Germicidal Spray Method," Test Organism: *Staphylococcus aureus* (ATCC 6538). For product Clean Smart. Study conducted at ATS Labs by Gracia Schroeder. Study completion date – October 24, 2013. Project Number A15677.**

The study was conducted against *Staphylococcus aureus* (ATCC 6538). Testing was conducted using three lots of test substance Clean Smart, Lot CS001, Lot CS002, and Lot CS003. Testing was performed according to the ATS Laboratory Protocol No. ECA02092413.GS (copy provided). The product was received as ready to use (RTU) spray. Initial broth cultures of the test organisms were prepared by inoculation of 10 µL aliquots from a thawed, vortex mixed stock cryovial to an initial 10 mL tube of Synthetic Broth growth medium and were incubated for 24±2 hours at 35-37°C. Following incubation, a 10µL aliquot of the culture was transferred to individual 20 x 150 mm Morton Closure tubes containing 10 mL of culture medium (Daily transfer #1). The final test culture was incubated for 48 – 54 hours at 35-37°C. All test cultures were vortexed and allowed to stand for ≥ 10 minutes prior to removing the upper portion of the culture for use in testing. No organic soil load was added. Individual glass slide carriers (18 mm x 36 mm) each in a Petri dish matted with two pieces of filter, were inoculated with 10.0 µL of test organism using a calibrated pipettor. The inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C and with 53.6% relative humidity. The carriers were used within 2 hours of drying. For each lot of test substance, test carriers were sprayed in a horizontal position with the test substance at a distance of 4-8 inches from the carrier surface for 8 sprays. The carriers were allowed to remain wet for 10 minutes at 22°C with 40% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at staggered intervals to 20 mL of Lethen Broth + 0.1% Sodium Thiosulfate to neutralize. The vessels were shaken thoroughly. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

**2. MRID 492603-06, "AOAC Germicidal Spray Method," Test Organism: *Salmonella enterica* (ATCC 10708). For product Clean Smart. Study conducted at ATS Labs by Gracia Schroeder. Study completion date – September 26, 2013. Project Number A15543.**

The study was conducted against *Salmonella enterica* (ATCC 10708). Testing was conducted using three Lots of test substance Clean Smart, Lot CS001, Lot CS002, and Lot CS003. Testing was performed according to the ATS Laboratory Protocol No. ECA02082613.GS.3 (copy provided). The product was received as ready to use (RTU) spray. Initial broth cultures of the test organisms were prepared by inoculation of 10 µL aliquots from a thawed, vortex mixed stock cryovial to an initial 10 mL tube of Synthetic Broth growth medium and were incubated for 24±2 hours at 35-37°C. Following incubation, a 10µL aliquot of the culture was transferred to individual 20 x 150 mm Morton Closure tubes containing 10 mL of culture medium (Daily transfer #1). Three additional daily transfers were prepared. The final test culture was incubated for 48 – 54 hours at 35-37°C. All test cultures were vortexed and allowed to stand for ≥ 10 minutes prior to removing the upper portion of the culture for use in testing. No soil load was

added. Individual glass slide carriers (18 mm x 36 mm) each in a Petri dish matted with two pieces of filter, were inoculated with 10.0 µL of test organism using a calibrated pipettor. The inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C and with 50% relative humidity. The carriers were used within 2 hours of drying. The test carriers were sprayed in a horizontal position with the test substance at a distance of 4-8 inches from the carrier surface for 5 sprays. The carriers were allowed to remain wet for 10 minutes at 22°C with 45% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at staggered intervals to 20 mL of Lethen Broth + 0.1% Sodium Thiosulfate to neutralize. The vessels were shaken thoroughly. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

**3. MRID 492603-07, "AOAC Germicidal Spray Method," Test Organism: *Pseudomonas aeruginosa* (ATCC 15442). For product Clean Smart. Study conducted at ATS Labs by Gracia Schroeder. Study completion date – September 26, 2013. Project Number A15541.**

The study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Testing was conducted using three Lots of test substance Brace, Lot CS001, Lot CS002 and Lot CS003. Testing was performed according to the ATS Laboratory Protocol No. ECA02082613.GS.1 (copy provided). The product was received as ready to use (RTU) spray. Initial broth cultures of the test organisms were prepared by inoculation of 10 µL aliquots from a thawed, vortex mixed stock cryovial to an initial 10 mL tube of Nutrient Broth growth medium and were incubated for 24±2 hours at 35-37°C. Following incubation, without vortex mixing the *Pseudomonas aeruginosa* culture, a 10µL aliquot of the culture was transferred to individual 20 x 150 mm Morton Closure tubes containing 10 mL of culture medium (Daily transfer #1). Three additional daily transfers were prepared. The final test culture was incubated for 48 – 54 hours at 35-37°C. On the day of use, the *Pseudomonas aeruginosa* culture pellicle was carefully aspirated by vacuum aspiration. Care was taken to avoid disrupting the pellicle. All test cultures were vortexed and allowed to stand for ≥ 10 minutes prior to removing the upper portion of the culture for use in testing. The culture was diluted by combining 2.00 mL of test organism suspension and 2.00 mL of growth medium. No soil load was added. Individual glass slide carriers (18 mm x 36 mm) each in a Petri dish matted with two pieces of filter, were inoculated with 10.0 µL of test organism using a calibrated pipettor. The inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C and with 50% relative humidity. The carriers were used within 2 hours of drying. The test carriers were sprayed in a horizontal position with the test substance at a distance of 4-8 inches from the carrier surface for 5 sprays. The carriers were allowed to remain wet for 10 minutes at 22°C with 44% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at staggered intervals to 20 mL of Lethen Broth + 0.1% Sodium Thiosulfate to neutralize. The vessels were shaken thoroughly. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or

absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

**4. MRID 492603-08, "AOAC Germicidal Spray Method," Test Organism: *Streptococcus pyogenes*, (ATCC 19615). For product Clean Smart. Study conducted at ATS Labs by Gracia Schroeder. Study completion date – August 29, 2013. Project Number A15433.**

The study was conducted against *Streptococcus pyogenes*, (ATCC 19615). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed in accordance with ATS Laboratory Protocol No. ECS02072213.GS.6 (copy provided). The product was received as ready to use (RTU) spray. From the stock plate, multiple Tryptic Soy agar plates with 5% sheep blood (BAP) were inoculated with the test organism. The plates were incubated for 2- 4 days at 35-37°C in CO<sub>2</sub>. Following incubation, the organism was suspended in Fluid Thioglycollate Medium to target 1 x 10<sup>8</sup> CFU/mL. The final test culture was mixed thoroughly prior to use. No organic soil load was added. Individual glass slide carriers (18 mm x 36 mm) each in a Petri dish matted with two pieces of filter were inoculated with 10.0 µL of test organism using a calibrated pipettor. The inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 25-30°C with 65% relative humidity. The carriers were used within 2 hours of drying. Test carriers were sprayed in a horizontal position with the test substance at a distance of 4-8 inches from the carrier surface for 5 sprays. The carriers were allowed to remain wet for 10 minutes at 22°C with 55% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps to 20 mL of Brain Heart Infusion Broth + 0.07% Lecithin + 0.5% Tween 80 to neutralize. The vessel was shaken thoroughly. Within 25 – 60 minutes of the initial (primary) transfer, the carriers were transferred to 20 mL of secondary neutralizing media containing Brain Heart Infusion Broth + 0.07% Lecithin + 0.5% Tween 80. All subcultures were incubated for 48±2 hours at 35-37°C in CO<sub>2</sub>. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: No protocol deviation or amendments were required for this study.

**5. MRID 492603-09, "AOAC Germicidal Spray Method," Test Organism: Vancomycin Resistant *Enterococcus faecalis* - VRE (ATCC 51575). For product Clean Smart. Study conducted at ATS Labs by Gracia Schroeder. Study completion date – September 5, 2013. Project Number A15432.**

The study was conducted against Vancomycin Resistant *Enterococcus faecalis* - VRE (ATCC 51575). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed according to ATS Laboratory Protocol No. ECA02072213.GS.4 (copy provided). The product was received as ready to use (RTU) spray. A loopful of the stock slant culture was transferred to an initial 10 mL tube of Fluid Thioglycollate growth medium, mixed, and incubated for 24±2 hours at 35-37°C. A 10 µL aliquot of this culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). One additional daily transfer was prepared. The final test culture was incubated for 48-54 hours at 35-37°C and was

mixed thoroughly prior to use. The test culture was vortexed and allowed to stand for  $\geq 10$  minutes prior to removing the upper portion leaving behind any clumps or debris and pooling the cultures in a sterile vessel for use in testing. No organic soil load was added. Individual glass slide carriers (18 mm x 36 mm) each in a Petri dish matted with two pieces of filter were inoculated with 10.0  $\mu\text{L}$  of test organism using a calibrated pipettor. The inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 25-30°C with 65% relative humidity. The carriers were used within 2 hours of drying. The test carriers were sprayed in a horizontal position with the test substance at a distance of 4-8 inches from the carrier surface for 5 sprays. The carriers were allowed to remain wet for 10 minutes at 23.4°C with 45.3% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at staggered intervals to 20 mL of Letheen Broth + 0.1% Sodium Thiosulfate to neutralize. The vessels were shaken thoroughly. All subcultures were incubated for 48 $\pm$ 2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Antimicrobial susceptibility testing was performed by ATS Labs for Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575) to verify the antibiotic resistance pattern. The Kirby Bauer susceptibility assay was performed utilizing a representative culture from the day of testing and using vancomycin antibiotic disks to confirm resistance.

Note: No protocol deviation or amendments were required for this study.

**6. MRID 492603-10, "AOAC Germicidal Spray Method," Test Organism: Methicillin Resistant *Staphylococcus aureus*- MRSA (ATCC 33592). For product Clean Smart. Study conducted at ATS Labs by Gracia Schroeder. Study completion date – August 29, 2013. Project Number A15430.**

The study was conducted Methicillin Resistant *Staphylococcus aureus*- MRSA (ATCC 33592). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed according to ATS Laboratory Protocol No. ECA02072213.GS.2 (copy provided). The product was received as ready to use (RTU) spray. A loopful of the stock slant culture was transferred to an initial 10 mL tube of Synthetic Broth growth medium, mixed, and incubated for 24 $\pm$ 2 hours at 35-37°C. A 10  $\mu\text{L}$  aliquot of this culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). One additional daily transfer was prepared. The final test culture was incubated for 48-54 hours at 35-37°C and was mixed thoroughly prior to use. The test culture was vortexed and allowed to stand for  $\geq 10$  minutes prior to removing the upper portion leaving behind any clumps or debris and pooling the cultures in a sterile vessel for use in testing. No organic soil load was added. Individual glass slide carriers (18 mm x 36 mm) each in a Petri dish matted with two pieces of filter were inoculated with 10.0  $\mu\text{L}$  of test organism using a calibrated pipettor. The inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 31 minutes at 35-37°C with 50% relative humidity. The carriers were used within 2 hours of drying. The test carriers were sprayed in a horizontal position with the test substance at a

distance of 4-8 inches from the carrier surface for 5 sprays. The carriers were allowed to remain wet for 10 minutes at 21.3°C with 49% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at staggered intervals to 20 mL of Lethen Broth + 0.1% Sodium Thiosulfate to neutralize. The vessels were shaken thoroughly. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Antimicrobial susceptibility testing was performed by ATS Labs to verify the antibiotic resistance pattern. The Kirby Bauer susceptibility assay was performed utilizing a representative culture from the day of testing and using oxacillin antibiotic disks to confirm resistance.

**7. MRID 492603-11, "AOAC Germicidal Spray Method," Test Organism: *Listeria monocytogenes* (ATCC 19117). For product Clean Smart. Study conducted at ATS Labs by Gracia Schroeder. Study completion date – September 05, 2013. Project Number A15446.**

The study was conducted against *Listeria monocytogenes* (ATCC 19117). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed according to ATS Laboratory Protocol No. ECA02072213.GS.5 (copy provided). The product was received as ready to use (RTU) spray. A loopful of the stock slant culture was transferred to an initial 10 mL tube of Brain Heart Infusion broth, mixed, and incubated for 24±2 hours at 35-37°C. A 10 µL aliquot of this culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). Three addition daily transfers were prepared. The final test culture was incubated for 48-54 hours at 35-37°C and was mixed thoroughly prior to use. The test culture was vortexed and allowed to stand for ≥10 minutes prior to removing the upper portion leaving behind any clumps or debris and pooling the cultures in a sterile vessel for use in testing. No organic soil load was added. Individual glass slide carriers (18 mm x 36 mm) each in a Petri dish matted with two pieces of filter were inoculated with 10.0 µL of test organism using a calibrated pipettor. The inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C with 40% relative humidity. The carriers were used within 2 hours of drying. Test carriers were sprayed in a horizontal position with the test substance at a distance of 4-8 inches from the carrier surface for 5 sprays. The carriers were allowed to remain wet for 10 minutes at 22°C with 49% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at staggered intervals to primary neutralizing solution containing 20 mL of Brain Heart Infusion Broth + 0.07% Lecithin + 0.5% Tween 80. Within approximately 25-60 minutes of the initial transfer, the carriers were transferred into individual secondary neutralizing solution containing 20 mL of Brain Heart Infusion Broth + 0.07% Lecithin + 0.5% Tween 80. The vessels were shaken thoroughly. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: No protocol deviations occurred during this study.

**8. MRID 492603-12 “Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces,” Virus: Herpes Simplex Virus Type 1 for product Clean Smart, by Shanen Conway. Study conducted at ATS Labs. Study completion date – September 11, 2013. Project Number A15443.**

The study was conducted against the F(1) Strain of Herpes simplex virus Type 1 (ATCC VR-733). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed in accordance with ATS Laboratory Protocol No. ECA02072413.HSV1 (copy provided). On the day of testing, one aliquot of stock virus (ATS Labs Lot H77) was thawed and maintained at refrigerated temperature until used in the assay. The stock virus culture was adjusted with fetal bovine serum to yield a 1% organic soil load. Rabbit kidney (RK) cells (obtained from Laboratory Research Services, Inc., St. Paul, MN) were used as the host cell line. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM), supplemented with 5% heat inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Films of virus were prepared at staggered intervals by spreading 200 µL of virus uniformly over the bottoms of 100 x 15 mm sterile glass Petri dishes. The virus films were dried at 20.0°C for 20 minutes at 50% relative humidity. For each lot of test substance, one dried virus film was thoroughly sprayed with test substance for 4 sprays at a distance of 4-8 inches and held covered for 10 minutes at 20.0°C. Near the end of the exposure time, the dried films were scraped with a cell scraper and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates ( $10^{-1}$  dilution) were then titrated by 10-fold serial dilution and were assayed for infectivity. The RK cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions from the test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub>. The cultures were scored periodically for seven (7) days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.

Note: No protocol deviations or amendments were reported for this study.

**9. MRID 492603-13 “Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces,” Virus: Herpes Simplex Virus Type 2 for product Clean Smart, by Shanen Conway. Study conducted at ATS Labs. Study completion date – August 30, 2013. Project Number A15429.**

The study was conducted against the G Strain of Herpes simplex virus Type 2 (ATCC VR-734). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed in accordance with ATS Laboratory Protocol No. ECA02072413.HSV2 (copy provided). On the day of testing, one aliquot of stock virus (ATS Labs Lot H2-69) was thawed and maintained at refrigerated temperature until used in the assay. The stock virus culture was adjusted with fetal bovine serum to yield a 1% organic soil load. Rabbit kidney (RK) cells (obtained from Laboratory Research Services, Inc., St. Paul, MN) were used as the host cell line. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM), supplemented with 5% heat inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Films of virus were prepared at staggered intervals by spreading 200 µL of virus uniformly over the bottoms of 100 x 15

mm sterile glass Petri dishes. The virus films were dried at 20.0°C for 20 minutes at 50% relative humidity. For each lot of test substance, one dried virus film was thoroughly sprayed with test substance for 4 sprays at a distance of 4-8 inches and held covered for 10 minutes at 20.0°C. Near the end of the exposure time, the dried films were scraped with a cell scraper and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates ( $10^{-1}$  dilution) were then titered by 10-fold serial dilution and were assayed for infectivity. The RK cells in multiwell culture dishes were inoculated in quadruplicate with 100  $\mu$ L of the dilutions from the test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub>. The cultures were scored periodically for seven (7) days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.

Note: No protocol deviations or amendments were reported for this study.

**10. MRID 492603-14 “Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces,” Virus: Human Immunodeficiency Virus Type 1 for product Clean Smart, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – September 16, 2013. Project Number A15434.**

The study was conducted against the HTLV-III<sub>B</sub> Strain of Human Immunodeficiency Virus Type 1 (HIV-1) (obtained from Advanced Biotechnologies, Inc., Columbia, MD). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed in accordance with ATS Laboratory Protocol No. ECA02072413.HIV (copy provided). On the day of testing, one aliquot of stock virus (ATS Labs Lot HIV-11) was thawed and maintained at refrigerated temperature until used in the assay. The stock virus culture was adjusted with fetal bovine serum to yield a 1% organic soil load. MT-2 (human T-cell leukemia) cells (obtained from AIDS Research and Reference Reagent Program, Division of AIDS, NIAID, NIH from Dr. Douglas Richman) were used as the host cell line. Test medium used to maintain the cell cultures was RPMI-1640, supplemented with 15% heat inactivated fetal bovine serum, 50  $\mu$ g/mL gentamicin, and 2.0 mM L-glutamine. Films of virus were prepared at staggered intervals by spreading 200  $\mu$ L of virus uniformly over the bottoms of 100 x 15 mm sterile glass Petri dishes. The virus films were dried at 25.0°C for 20 minutes at 42.4% relative humidity. For each lot of test substance, one dried virus film was thoroughly sprayed with test substance for 4 sprays at a distance of 4-8 inches and held covered for 10 minutes at 19.0°C. Near the end of the exposure time, the dried films were scraped with a cell scraper and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates ( $10^{-1}$  dilution) were then titered by 10-fold serial dilution and were assayed for infectivity. The MT-2 cells in multiwell culture dishes were inoculated in quadruplicate with 200  $\mu$ L of the dilutions from the test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub>. The cultures were scored periodically for fourteen (14) days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.

Note: No protocol deviations or amendments were reported for this study.

**11. MRID 492603-15 “Virucidal Efficacy of a Disinfectant for Use on Inanimate**

**Environmental Surfaces,” Virus: Influenza A (H1N1) Virus for product Clean Smart, by Shanen Conway. Study conducted at ATS Labs. Study completion date – August 30, 2013. Project Number A15428.**

The study was conducted against the A/PR/8/34 Strain of Influenza A (H1N1) (ATCC VR-1469). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed in accordance with ATS Laboratory Protocol No. ECA02072413.FLUA (copy provided). On the day of testing, one aliquot of stock virus (ATS Labs Lot FLUA-35) was thawed and maintained at refrigerated temperature until used in the assay. The stock virus culture was adjusted with fetal bovine serum to yield a 1% organic soil load. Rhesus monkey kidney (RMK) cells (obtained from Diagnostic Hybrids, Athens, OH) were used as the host cell line. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM), supplemented with 1% heat inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Films of virus were prepared at staggered intervals by spreading 200 µL of virus uniformly over the bottoms of 100 x 15 mm sterile glass Petri dishes. The virus films were dried at 20.0°C for 20 minutes at 40% relative humidity. For each lot of test substance, one dried virus film was thoroughly sprayed with test substance for 4 sprays at a distance of 4-8 inches and held covered for 10 minutes at 20°C. Near the end of the exposure time, the dried films were scraped with a cell scraper and the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates (10<sup>-1</sup> dilution) were then titered by 10-fold serial dilution and were assayed for infectivity. The RMK cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions from the test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub>. The cultures were scored periodically for seven (7) days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.

Note: No protocol deviations or amendments were reported for this study.

**12. MRID 492603-16 “Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces,” Virus: Rhinovirus Type 37 for product Clean Smart, by Shanen Conway. Study conducted at ATS Labs. Study completion date – September 19, 2013. Project Number A15534.**

The study was conducted against the 151-1 Strain of Rhinovirus Type 37 (ATCC VR-1147). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed in accordance with ATS Laboratory Protocol No. ECA02090313.R37 (copy provided). On the day of testing, one aliquot of stock virus (ATS Labs Lot NR37-28) was thawed and maintained at refrigerated temperature until used in the assay. The stock virus culture was adjusted with fetal bovine serum to yield a 1% organic soil load. MRC-5 (human embryonic lung) cells (ATCC CCL-171) were used as the host cell line. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM), supplemented with 10% heat inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Films of virus were prepared at staggered intervals by spreading 200 µL of virus uniformly over the bottoms of 100 x 15 mm sterile glass Petri dishes. The virus films were dried at 20.0°C for 20 minutes at 50% relative humidity. For each lot of test substance, one dried virus film was thoroughly sprayed with test substance for

4 sprays at a distance of 4-8 inches and held covered for 10 minutes at 20°C. Near the end of the exposure time, the dried films were scraped with a cell scraper and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates ( $10^{-1}$  dilution) were then titrated by 10-fold serial dilution and were assayed for infectivity. The MRC-5 cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions from the test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub>. The cultures were scored periodically for seven (7) days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.

Note: The reported protocol amendments were found to be acceptable. No protocol deviations were reported for this study.

**13. MRID 492603-17 “Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces,” Virus: Human Coronavirus for product Clean Smart, by Shanen Conway. Study conducted at ATS Labs. Study completion date – September 13, 2013. Project Number A15421.**

The study was conducted against the 229E strain of Human Coronavirus (ATCC VR-740). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed in accordance with ATS Laboratory Protocol No. ECA02072413.COR (copy provided). On the day of testing, one aliquot of stock virus (ATS Labs Lot HCV-69) was thawed and maintained at refrigerated temperature until used in the assay. The stock virus culture was adjusted with fetal bovine serum to yield a 1% organic soil load. WI-38 (human lung) cells (ATCC CCL-75) were used as the host cell line. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM), supplemented with 2% heat inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Films of virus were prepared at staggered intervals by spreading 200 µL of virus uniformly over the bottoms of 100 x 15 mm sterile glass Petri dishes. The virus films were dried at 20.0°C for 20 minutes at 50% relative humidity. For each lot of test substance, one dried virus film was thoroughly sprayed with test substance for 4 sprays at a distance of 4-8 inches and held covered for 10 minutes at 20.0°C. Near the end of the exposure time, the dried films were scraped with a cell scraper and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates ( $10^{-1}$  dilution) were then titrated by 10-fold serial dilution and were assayed for infectivity. The WI-38 cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions from the test and control groups and were incubated at 31-35°C in a humidified atmosphere of 5-7% CO<sub>2</sub>. The cultures were scored periodically for twelve (12) days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.

Note: No protocol deviations or amendments were reported for this study.

**14. MRID 492603-18 “Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces,” Virus: Respiratory Syncytial Virus for product Clean Smart, by Shanen Conway. Study conducted at ATS Labs. Study completion**

**date – September 27, 2013. Project Number A15444.**

The study was conducted against the Long strain of Respiratory syncytial virus (RSV) (ATCC VR-26). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed in accordance with ATS Laboratory Protocol No. ECA02072413.RSV (copy provided). On the day of testing, one aliquot of stock virus (ATS Labs Lot NRSV-30) was thawed and maintained at refrigerated temperature until used in the assay. The stock virus culture was adjusted with fetal bovine serum to yield a 1% organic soil load. Films of virus were prepared at staggered intervals by spreading 200 µL of virus uniformly over the bottoms of 100 x 15 mm sterile glass Petri dishes. The virus films were dried at 20.0°C for 20 minutes at 50% relative humidity. For each lot of test substance, one dried virus film was thoroughly sprayed with test substance for 4 sprays at a distance of 4-8 inches and held covered for 10 minutes at 20.0°C. Near the end of the exposure time, the dried films were scraped with a cell scraper and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates (10<sup>-1</sup> dilution) were then titered by 10-fold serial dilution and were assayed for infectivity. The Hep-2 cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions from the test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub>. The cultures were scored periodically for nine (9) days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.

Note: No protocol deviations or amendments were reported for this study.

**15. MRID 492603-19, "Fungicidal Germicidal Spray Method," Test Organism: *Trichophyton mentagrophytes*, (ATCC 9533). For product Clean Smart. Study conducted at ATS Labs by Anne Stemper. Study completion date – September 16, 2013. Project Number A15449.**

The study was conducted against *Trichophyton mentagrophytes*, (ATCC 9533). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed in accordance with ATS Laboratory Protocol No. ECA02072413.FGS.1 (copy provided). The product was received as ready to use (RTU) spray. From a stock culture of the test organism, 30 Sabouraud Dextrose Agar plates were inoculated and incubated at 25-30°C for 10 days. The mycelia were removed using a sterile device and a conidia suspension was prepared. The conidia suspension was passed through sterile gauze to remove hyphal fragments. The conidial count estimated using a hemacytometer was 8.8x10<sup>7</sup> conidia/mL. The test culture was mixed thoroughly prior to use. No organic soil load was added. Individual glass slide carriers (18 mm x 36 mm) each in a Petri dish matted with two pieces of filter were inoculated with 10.0 µL of test organism using a calibrated pipettor. The inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C with 50% relative humidity. The carriers were used within 2 hours of drying. Test carriers were sprayed in a horizontal position with the test substance at a distance of 4-8 inches from the carrier surface for 5 sprays. The carriers were allowed to remain wet for 10 minutes at 23.8°C with 36.8% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at staggered intervals to

20 mL of Sabouraud Dextrose Broth + 0.07% Lecithin + 0.5% Tween 80 to neutralize. Within 25 – 60 minutes of the initial transfer, the individual carriers were transferred to 20 mL of secondary neutralizing subculture medium Sabouraud Dextrose Broth + 0.07% Lecithin + 0.5% Tween 80. The vessel was shaken thoroughly. All neutralized subcultures were incubated for 10 days at 25-30°C. The Potato Dextrose agar plate subcultures were incubated for 44-76 hours at 25-30°C. The subculture plates were stored at 2-8°C for one day and the subculture broths were stored at 2-8°C for two days prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: No protocol deviations were required for this study.

**16. MRID 492603-20, “AOAC Germicidal Spray Method,” Test Organism: *Escherichia coli* (ATCC 11229). For product Clean Smart. Study conducted at ATS Labs by Gracia Schroeder. Study completion date – August 27, 2013. Project Number A15427.**

The study was conducted against *Escherichia coli* (ATCC 11229). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed according to using ATS Laboratory Protocol No. ECA02072413.GS (copy provided). The product was received as ready to use (RTU) spray. A loopful of the stock slant culture was transferred to an initial 10 mL tube of Synthetic Broth, mixed, and incubated for 24±2 hours at 35-37°C. A 10 µL aliquot of this culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). One additional daily transfer was prepared. The final test culture was incubated for 48-54 hours at 35-37°C and was mixed thoroughly prior to use. The test culture was vortexed and allowed to stand for ≥10 minutes prior to removing the upper portion leaving behind any clumps or debris and pooling the cultures in a sterile vessel for use in testing. No organic soil load was added. Individual glass slide carriers (18 mm x 36 mm) each in a Petri dish matted with two pieces of filter, were inoculated with 10.0 µL of test organism using a calibrated pipettor. The inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C and with 50% relative humidity. The carriers were used within 2 hours of drying. For each lot of test substance, test carriers were sprayed in a horizontal position with the test substance at a distance of 4-8 inches from the carrier surface for 5 sprays. The carriers were allowed to remain wet for 10 minutes at 23°C with 53% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at staggered intervals to 20 mL of Lethen Broth + 0.1% Sodium Thiosulfate to neutralize. The vessels were shaken thoroughly. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

**17. MRID 492603-21, “Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application)” Test Organism: *Staphylococcus aureus* (ATCC 6538). For product Clean Smart. Study conducted at ATS Labs by Gracia Schroeder. Study completion date – October 24, 2013. Project Number**

#### **A15678.**

The study was conducted against *Staphylococcus aureus* (ATCC 6538). Testing was conducted using three lots of test substance Clean Smart, Lot CS001, Lot CS002, and Lot CS003. Testing was performed according to ATS Laboratory Protocol No. ECA02092413.NFS.1 (copy provided). The product was received as ready to use (RTU) spray. Initial broth cultures of the test organisms were prepared by inoculation of Nutrient Broth growth medium for the initial suspension. From the initial suspension, a minimum of three daily loopful (10 µL) transfers of culture into 10 mL of Nutrient Broth was performed and each was incubated for 24 ± 2 hours. The final test culture was incubated for 48 – 54 hours at 35-37°C. All test cultures were vortexed and allowed to stand for ≥ 15 minutes prior to removing the upper portion of the culture for use in testing. No organic soil load was added. Individual glass carriers (1" x 1") were inoculated with 20.0 µL of test organism using a calibrated pipettor. The inoculum was spread to within 3 mm of the edges of the carrier. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 35 minutes at 35-37°C and with 40% relative humidity. The test carriers were sprayed with the test substance at a distance of 4-8 inches from the carrier surface for 8 sprays. The carriers were allowed to remain wet for 5 minutes at 21°C with 42% relative humidity. Following the exposure period, the individual carriers were transferred to 20 mL of Lethen Broth + 0.1% Sodium Thiosulfate to neutralize. The jars were vortexed to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00 mL and 0.100 mL aliquots of neutralized solution (10°) were plated onto Tryptic Soy Agar with 5% Sheep Blood medium. All subcultures were incubated for 48±4 hours at 35-37°C prior to visual enumeration. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

**18. MRID 492603-22, "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application)" Test Organism: *Enterobacter aerogenes* (ATCC 13048). For product Clean Smart. Study conducted at ATS Labs by Gracia Schroeder. Study completion date – October 24, 2013. Project Number A15679.**

The study was conducted against *Enterobacter aerogenes* (ATCC 13048). Testing was conducted using three lots of test substance Clean Smart, Lot CS001, Lot CS002, and Lot CS003. Testing was performed according to ATS Laboratory Protocol No. ECA02092413.NFS.2 (copy provided). The product was received as ready to use (RTU) spray. Initial broth cultures of the test organisms were prepared by inoculation of Tryptic Soy Broth growth medium for the initial suspension. From the initial suspension, a minimum of three daily loopful (10 µL) transfers of culture into 10 mL of Tryptic Soy Broth was performed and each was incubated for 24 ± 2 hours. The final test culture was incubated for 48 – 54 hours at 35-37°C. All test cultures were vortexed and allowed to stand for ≥ 15 minutes prior to removing the upper portion of the culture for use in testing. No organic soil load was added. Individual glass carriers (1" x 1") were inoculated with 20.0 µL of test organism using a calibrated pipettor. The inoculum was spread to within 3 mm of the edges of the carrier. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 35 minutes at 35-37°C and with 41% relative humidity. The test carriers were sprayed with the test substance at a distance of 4-8 inches from the carrier surface for 8 sprays. The carriers

were allowed to remain wet for 5 minutes at 22°C with 41% relative humidity. Following the exposure period, the individual carriers and excess liquid were transferred to 20 mL of Lethen Broth + 0.1% Sodium Thiosulfate to neutralize. The jars were vortexed to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00 mL and 0.100 mL aliquots of neutralized solution (10°) were plated onto Tryptic Soy Agar with 5% Sheep Blood medium. All subcultures were incubated for 48±4 hours at 25-30°C prior to visual enumeration. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

**19. MRID 492603-23, “Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application)” Test Organism: *Streptococcus pneumoniae* (ATCC 6305). For product Clean Smart. Study conducted at ATS Labs by Jill Ruhme. Study completion date – September 11, 2013. Project Number A15442.**

The study was conducted against *Streptococcus pneumoniae* (ATCC 6305). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed according to ATS Laboratory Protocol No. ECA02071913.NFS.6 (copy provided). The product was received as ready to use (RTU) spray. Initial broth cultures of the test organisms were prepared by inoculation of multiple Tryptic Soy Agar with 5% Sheep Blood plate and incubating for 2-4 days at 35-37°C. Following incubation, an organism suspension was prepared in Fluid Thioglycollate medium that target  $1 \times 10^8$  CFU/mL. No organic soil load was added. The test culture is used within three hours of preparation. Individual glass carriers (1" x 1") were inoculated with 20.0 µL of test organism using a calibrated pipettor. The inoculum was spread to within 3 mm of the edges of the carrier. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 20-40 minutes at 35-37°C and with 40-41% relative humidity. The test carriers were sprayed with the test substance at a distance of 4-8 inches from the carrier surface for 8 sprays. The carriers were allowed to remain wet for 30 seconds at 22°C with 41% relative humidity. Following the exposure period, the individual carriers and excess liquid were transferred to 20 mL of Lethen Broth + 0.1% Sodium Thiosulfate to neutralize. The jars were vortexed to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00 mL and 0.100 mL aliquots of neutralized solution (10°) were plated onto Tryptic Soy Agar with 5% Sheep Blood medium. All subcultures were incubated for 48±4 hours at 35-37°C prior to visual enumeration. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

**20. MRID 492603-24, “Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application)” Test Organism: *Salmonella enterica* (ATCC 10708). For product Clean Smart. Study conducted at ATS Labs by Joshua Luedtke. Study completion date – September 4, 2013. Project Number A15441.**

The study was conducted against *Salmonella enterica* (ATCC 10708). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed according to ATS Laboratory Protocol No. ECA02071913.NFS.3 (copy provided). The product was received as ready to use (RTU) spray. Initial broth cultures of the test organisms were prepared by inoculation of Nutrient Broth growth

medium for the initial suspension. From the initial suspension, a minimum of three daily loopful (10 µL) transfers of culture into 10 mL of Nutrient Broth were performed and each was incubated for 24 ± 2 hours. The final test culture was incubated for 48 – 54 hours at 35-37°C. All test cultures were vortexed and allowed to stand for ≥ 15 minutes prior to removing the upper portion of the culture for use in testing. No organic soil load was added. Individual glass carriers (1" x 1") were inoculated with 20.0 µL of test organism using a calibrated pipettor. The inoculum was spread to within 3 mm of the edges of the carrier. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C and with 40% relative humidity. The test carriers were sprayed with the test substance at a distance of 4-8 inches from the carrier surface for 5 sprays. The carriers were allowed to remain wet for 30 seconds at 22°C with 58% relative humidity. Following the exposure period, the individual carriers and excess liquid were transferred to 20 mL of Lethen Broth + 0.1% Sodium Thiosulfate to neutralize. The jars were vortexed to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00 mL and 0.100 mL aliquots of neutralized solution (10°) were plated onto Tryptic Soy Agar with 5% Sheep Blood medium. All subcultures were incubated for 48±4 hours at 35-37°C prior to visual enumeration. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: The protocol amendments were found to be acceptable. There were not any protocol deviations reported.

**21. MRID 492603-25, "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application" Test Organism: Methicillin Resistant *Staphylococcus aureus*- MRSA (ATCC 33592). For product Clean Smart. Study conducted at ATS Labs by Joshua Luedtke. Study completion date – September 6, 2013. Project Number A15447.**

The study was conducted against Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592). Testing was conducted using two lots of test substance Clean Smart, Lot CS001 and Lot CS002. Testing was performed according to ATS Laboratory Protocol No. ECA02071913.NFS.4 (copy provided). The product was received as ready to use (RTU) spray. Initial broth cultures of the test organisms were prepared by inoculation of Synthetic Broth growth medium for the initial suspension. From the initial suspension, a minimum of three daily loopful (10 µL) transfers of culture into 10 mL of Synthetic Broth were performed and each was incubated for 24 ± 2 hours. The final test culture was incubated for 48 – 54 hours at 35-37°C. All test cultures were vortexed and allowed to stand for ≥ 15 minutes prior to removing the upper portion of the culture for use in testing. No organic soil load was added. Individual glass carriers (1" x 1") were inoculated with 20.0 µL of test organism using a calibrated pipettor. The inoculum was spread to within 3 mm of the edges of the carrier. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 35 minutes at 35-37°C and with 40% relative humidity. The test carriers were sprayed with the test substance at a distance of 4-8 inches from the carrier surface for 5 sprays. The carriers were allowed to remain wet for 30 seconds at 22.2°C with 43.59% relative humidity. Following the exposure period, the individual carriers and excess liquid were transferred to 20 mL of Lethen Broth + 0.1% Sodium Thiosulfate to neutralize. The jars were vortexed to suspend the surviving organisms. Within 30 minutes of neutralization,

duplicate 1.00 mL and 0.100 mL aliquots of neutralized solution (10<sup>9</sup>) were plated onto Tryptic Soy Agar with 5% Sheep Blood medium. All subcultures were incubated for 48±4 hours at 35-37°C. The subcultures were placed at 2-8°C for two days. Following incubation and storage, the subcultures were visually enumerated. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Antibiotic susceptibility testing was performed by ATS Labs using the Kirby Bauer susceptibility assay. Oxacillin antibiotic disks were used to verify antimicrobial resistance pattern.

Note: The protocol amendments were found to be acceptable. There were not any protocol deviations reported.

**22. MRID 492603-26, "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-food Contact Surfaces (Modification of Spray Product Application", Test Organism: Vancomycin Resistant *Enterococcus faecalis*- VRE (ATCC 51575)", for product Clean Smart, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – September 03, 2013. Project Number A15440.**

The study was conducted against Vancomycin Resistant *Enterococcus faecalis*-VRE (ATCC 51575). Two lots of the product Clean Smart, Lot CS001 and Lot CS002, were tested using the provided ATS Labs protocol ECA02071913.NFS.2 marked as proprietary information. The product was received as a ready-to-use trigger spray. The test culture was prepared by inoculating 10 mL of Fluid Thioglycollate media from a stock slant with no more than 5 transfers from freeze and ≤30 days old. Daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL from the initial broth suspension into 10 mL of culture media were performed. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper portions were removed of the 48 - 54 hours cultures of the test system after vortex and settling for ≥10 minutes occurred. No soil load was added. Glass carriers (1" X 1") were inoculated uniformly spread over the entire carrier slide with 20 µL of the 48 - 54 hours old suspension of test organism. The carriers were dried for 21 minutes at 35 - 37°C with 40% relative humidity. Each carrier was sprayed with the product for 5 sprays at a distance of 4-8 inches from the carrier surface. Each carrier remained in contact with the product for 30 seconds at 23.1°C with 45.6% relative humidity. Following exposure, the individual carriers and excess liquid in each Petri dish were transferred to 20 mL of Letheen Broth + 0.1% Sodium Thiosulfate to neutralize. The jars were vortexed to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00 mL and 0.100 mL aliquots of the neutralized solution (10<sup>9</sup>) were plated onto the recovery Tryptic Soy Agar with 5% Sheep Blood. All subcultures were incubated for 48 ± 4 hours at 35 - 37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, antibiotic resistance confirmation, and carrier population.

Note- ATS Labs verified Vancomycin Resistant *Enterococcus faecalis* is resistant to vancomycin by performing a Kirby Bauer Susceptibility assay. Oxacillin antibiotic disks were used to verify antimicrobial resistance pattern.

**23. MRID 492603-27, “Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-food Contact Surfaces (Modification of Spray Product Application”, Test Organism: *Escherichia coli* (ATCC 11229)”, for product Clean Smart, by Anne Stemper. Study conducted at ATS Labs. Study completion date – August 30, 2013. Project Number A15448.**

The study was conducted against *Escherichia coli* (ATCC 11229). Two lots of the product Clean Smart, Lot CS001 and Lot Lot CS002, were tested using the provided ATS Labs protocol ECA02071913.NFS.5 marked as proprietary information. The product was received as a ready-to-use trigger spray. The test culture was prepared by inoculating 10 mL of Synthetic Broth from a stock slant with no more than 5 transfers from freeze and ≤30 days old. Daily consecutive transfers of a minimum of three but less than thirty transfers of 10 µL from the initial broth suspension into 10 mL of culture media were performed. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper portions were removed of the 48 - 54 hours cultures of the test system after vortex and settling for ≥10 minutes occurred. No soil load was added. Glass carriers (1" X 1") were inoculated uniformly spread over the entire carrier slide with 20 µL of the 48 - 54 hours old suspension of test organism. The carriers were dried for 30 minutes at 35 - 37°C with 40% relative humidity. Each carrier was sprayed with the product for 5 sprays at a distance of 4-8 inches from the carrier surface. Each carrier remained in contact with the product for 30 seconds at 22°C with 49% relative humidity. Following exposure, the individual carriers and excess liquid in each Petri dish were transferred to 20 mL of Lethen Broth + 0.01% Sodium Thiosulfate to neutralize. The jars were vortexed to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00 mL and 0.100 mL aliquots of the neutralized solution (10°) were plated onto the recovery Tryptic Soy Agar with 5% Sheep Blood. All subcultures were incubated for 48 ± 4 hours at 35 - 37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, antibiotic resistance confirmation, and carrier population.

**24. MRID 492603-28 “AOAC Available Chlorine in Disinfectants” against *Staphylococcus aureus* (ATCC 6538), for Clean Smart 01, by Matthew Sathe; Project number: A15457. Study conducted at ATS Labs. Study completed on September 6, 2013.**

This study was conducted against *Staphylococcus aureus* (ATCC 6538) grown in Nutrient Broth. Three lots (CS001, CS002, and CS003) of the product, Clean Smart 01, were tested according to ATS Labs Protocol No. ECA02072213.AVC.2 (copy provided). The product was received ready-to-use. Sodium hypochlorite (NaOCl) was used as the data control standard at three concentrations, 200 ppm (titrated at 199 ppm), 100 ppm, and 50 ppm. Lethen Broth with 0.07% Lecithin and 0.5% Tween 80 was used as neutralizer; and Tryptic Soy Agar with 5% sheep blood was used as agar plate medium. A 0.05 ml aliquot of the test culture was added to each (10 ml) of the test substance and control NaOCl solutions at 20±1°C. One minute after addition of the test organism, 10 µL of each medicated and control culture was transferred to 10 ml of neutralizing subculture medium. Each tube was then challenged with additional 0.05 ml aliquot of the test culture 30 seconds after subculturing. This process was repeated for a total of 10 subcultures for each lot and control. The neutralized subcultures were incubated for 48±2 hours at 35-37°C, stored at 2-8°C for one day, and examined for the presence or absence of visible growth. Representative neutralized subcultures showing growth were

subcultured, stained and/or biochemically assayed to confirm or rule out the presence of the test organism. Controls included neutralization, viability control, purity, initial suspension population and sterility. The reported colony forming units per ml in the initial suspension population is *Staphylococcus aureus*  $3.6 \times 10^8$ .

**25. MRID 492603-29 “AOAC Available Chlorine in Disinfectants” against *Salmonella enterica* serovar Typhi (ATCC 6539), for Clean Smart 01, by Matthew Sathe; Project number: A15456. Study conducted at ATS Labs. Study completed on September 5, 2013.**

This study was conducted against *Salmonella enterica* serovar Typhi (ATCC 6539) grown in Nutrient Broth. Three lots (CS001, CS002, and CS003) of the product, Clean Smart 01, were tested according to ATS Labs Protocol No. ECA02072213.AVC.1 (copy provided). The product was received ready-to-use. Sodium hypochlorite (NaOCl) was used as the data control standard at three concentrations, 200 ppm (titrated at 199 ppm), 100 ppm, and 50 ppm. Lethen Broth with 0.07% Lecithin and 0.5% Tween 80 was used as neutralizer; and Tryptic Soy Agar with 5% sheep blood was used as agar plate medium. A 0.05 ml aliquot of the test culture was added to each (10 ml) of the test substance and control NaOCl solutions at  $20 \pm 1^\circ\text{C}$ . One minute after addition of the test organism, 10  $\mu\text{L}$  of each medicated and control culture was transferred to 10 ml of neutralizing subculture medium. Each tube was then challenged with additional 0.05 ml aliquot of the test culture 30 seconds after subculturing. This process was repeated for a total of 10 subcultures for each lot and control. The neutralized subcultures were incubated for  $48 \pm 2$  hours at  $35\text{--}37^\circ\text{C}$ , stored at  $2\text{--}8^\circ\text{C}$  for one day, and examined for the presence or absence of visible growth. Representative neutralized subcultures showing growth were subcultured, stained and/or biochemically assayed to confirm or rule out the presence of the test organism. Controls included neutralization, viability control, purity, initial suspension population and sterility. The reported colony forming units per ml in the initial suspension population is *Salmonella enterica* serovar Typhi  $5.0 \times 10^8$ .

**26. MRID 492603-30 “AOAC Available Chlorine in Disinfectants” against *Escherichia coli* (ATCC 11229), for Clean Smart 01, by Jill Ruhme; Project number: A15458. Study conducted at ATS Labs. Study completed on September 13, 2013.**

This study was conducted against *Escherichia coli* (ATCC 11229) grown in Synthetic Broth. Two lots (CS001 and CS002) of the product, Clean Smart 01, were tested according to ATS Labs Protocol No. ECA02072213.AVC.3 (copy provided). The product was received ready-to-use. Sodium hypochlorite (NaOCl) was used as the data control standard at three concentrations, 200 ppm (titrated at 199 ppm), 100 ppm, and 50 ppm. Lethen Broth with 0.07% Lecithin and 0.5% Tween 80 was used as neutralizer; and Tryptic Soy Agar with 5% sheep blood was used as agar plate medium. A 0.05 ml aliquot of the test culture was added to each (10 ml) of the test substance and control NaOCl solutions at  $20 \pm 1^\circ\text{C}$ . One minute after addition of the test organism, 10  $\mu\text{L}$  of each medicated and control culture was transferred to 10 ml of neutralizing subculture medium. Each tube was then challenged with additional 0.05 ml aliquot of the test culture 30 seconds after subculturing. This process was repeated for a total of 10 subcultures for each lot and control. The neutralized subcultures were incubated for  $48 \pm 2$  hours at  $35\text{--}37^\circ\text{C}$ , stored at  $2\text{--}8^\circ\text{C}$  for one day, and examined for the presence or absence of visible growth. Representative neutralized subcultures showing growth were

subcultured, stained and/or biochemically assayed to confirm or rule out the presence of the test organism. Controls included neutralization, viability control, purity, initial suspension population and sterility. The reported colony forming units per ml in the initial suspension population is *Escherichia coli*  $8.0 \times 10^8$ .

## V. RESULTS:

MRID #	ORGANISM	RESULTS @10 Minutes Exposure Number of Carriers Exhibiting Growth/Total Number of Carriers Tested			Carrier Population Control (Average Log <sub>10</sub> )
		Lot CS001	Lot CS002	Lot CS003	
492603-05	<i>Staphylococcus aureus</i>	0/60	0/60	0/60	5.64
492603-06	<i>Salmonella enterica</i>	0/60	0/60	0/60	6.37
492603-07	<i>Pseudomonas aeruginosa</i>	0/60	0/60	0/60	6.09
492603-08	<i>Streptococcus pyogenes</i>	1°= 0/10 2°=0/10	1°= 0/10 2°=0/10		6.34
492603-09	<i>Enterococcus faecalis</i> -VRE	0/10	0/10		5.77
492603-10	<i>Staphylococcus aureus</i> -MRSA	0/10	0/10		6.21
492603-11	<i>Listeria monocytogenes</i>	1°= 0/10 2°=0/10	1°= 0/10 2°=0/10		4.75
492603-19	<i>Trichophyton mentagrophytes</i>	1°= 0/10 2°=0/10	1°= 0/10 2°=0/10		5.10
492603-20	<i>Escherichia coli</i>	0/10	0/10		5.84

MRID #	ORGANISM	RESULTS (Log) @10 Minutes Exposure			Dried Virus Control (Log)
		TCID <sub>50</sub> /	Lot CS001	Lot CS002	
492603-12	Herpes Simplex Virus Type 1	100µL	≤10 <sup>0.50</sup>	≤10 <sup>0.50</sup>	10 <sup>5.25</sup>
492603-13	Herpes Simplex Virus Type 2	100µL	≤10 <sup>0.50</sup>	≤10 <sup>0.50</sup>	10 <sup>4.50</sup>
492603-14	Human Immunodeficiency Type 1	200µL Cytotoxicity seen at 10 <sup>-1</sup>	≤10 <sup>1.50</sup>	≤10 <sup>1.50</sup>	10 <sup>5.50</sup>
492603-15	Influenza A (H1N1) Virus	100µL	≤10 <sup>0.50</sup>	≤10 <sup>0.50</sup>	10 <sup>6.50</sup>
492603-16	Rhinovirus Type 37	100µL	≤10 <sup>0.50</sup>	≤10 <sup>0.50</sup>	10 <sup>4.75</sup>
492603-17	Human Coronavirus	100µL	≤10 <sup>0.50</sup>	≤10 <sup>0.50</sup>	10 <sup>4.50</sup>
492603-18	Respiratory Syncytial Virus	100µL	≤10 <sup>0.50</sup>	≤10 <sup>0.50</sup>	10 <sup>4.75</sup>

MRID #	ORGANISM @5 minutes exposure	RESULTS			Carrier Population Geometric Mean (Average Log <sub>10</sub> )	% Reduction for all lots tested
		Geometric Mean CFU/Carrier (Log)				
		Lot CS001	Lot CS002	Lot CS003		
492603-21	<i>Staphylococcus aureus</i>	<2.00 X 10 <sup>1</sup>	<2.00 X 10 <sup>1</sup>	<2.00 X 10 <sup>1</sup>	2.69 X 10 <sup>6</sup>	>99.9%
492603-22	<i>Enterobacter aerogenes</i>	<2.00 X 10 <sup>1</sup>	<2.00 X 10 <sup>1</sup>	<2.00 X 10 <sup>1</sup>	1.70 X 10 <sup>7</sup>	>99.9%
MRID #	ORGANISM @ 30 seconds exposure					
492603-23	<i>Streptococcus pneumonia</i>	<2.63 X 10 <sup>1</sup>	<4.07 X 10 <sup>1</sup>		7.59 X 10 <sup>5</sup>	>99.9%
492603-24	<i>Salmonella enterica</i>	<2.00 X 10 <sup>1</sup>	<2.00 X 10 <sup>1</sup>		1.78 X 10 <sup>6</sup>	>99.9%
492603-25	<i>Staphylococcus aureus</i> -MRSA	<2.00 X 10 <sup>1</sup>	<2.00 X 10 <sup>1</sup>		3.47 X 10 <sup>6</sup>	>99.9%
492603-26	<i>Enterococcus faecalis</i> -VRE	<2.00 X 10 <sup>1</sup>	<2.00 X 10 <sup>1</sup>		2.14 X 10 <sup>6</sup>	>99.9%
492603-27	<i>Escherichia coli</i>	<2.00 X 10 <sup>1</sup>	<2.00 X 10 <sup>1</sup>		1.48 X 10 <sup>7</sup>	>99.9%

MRID	Test Organism	Test/Control Substance	Concentrati on or Lot	Subculture Number									
				1	2	3	4	5	6	7	8	9	10
492603-28	<i>Staphylococcus aureus</i> (ATCC 6538)	NaOCl	200 ppm	0	0	0	0	0	0	+	+	+	+
			100 ppm	0	0	0	0	+	+	+	+	+	+
			50 ppm	0	0	+	+	+	+	+	+	+	+
		Clean Smart 01	Lot CS001	0	0	0	0	0	0	0	0	0	+
			Lot CS002	0	0	0	0	0	0	0	0	0	0
			Lot CS003	0	0	0	0	0	0	0	0	0	+
492603-29	<i>Salmonella enterica</i> serovar Typhi (ATCC 6539)	NaOCl	200 ppm	0	0	0	0	0	0	+	+	+	+
			100 ppm	0	0	0	0	+	+	+	+	+	+
			50 ppm	0	0	+	+	+	+	+	+	+	+
		Clean Smart 01	Lot CS001	0	0	0	0	0	0	0	0	+	+
			Lot CS002	0	0	0	0	0	0	0	0	0	+
			Lot CS003	0	0	0	0	0	0	0	0	+	+
492603-30	<i>Escherichia coli</i> (ATCC 11229)	NaOCl	200 ppm	0	0	0	0	0	+	+	+	+	+
			100 ppm	0	0	+	+	+	+	+	+	+	+
			50 ppm	0	+	+	+	+	+	+	+	+	+
		Clean Smart 01	Lot CS001	0	0	0	0	0	0	+	+	+	+
			Lot CS002	0	0	0	0	0	0	0	+	+	+

+ = Growth of the test organism

0 = No growth of the test organism

## VI. CONCLUSIONS:

1.) The submitted efficacy data **does support** the use of the ready-to-use spray Clean Smart as a disinfectant against the following microorganisms on hard, non-porous surfaces with a 10-minute contact time:

<i>Staphylococcus aureus</i>	MRID 492603-05
<i>Salmonella enterica</i>	MRID 492603-06
<i>Pseudomonas aeruginosa</i>	MRID 492603-07
<i>Streptococcus pyogenes</i>	MRID 492603-08
<i>Enterococcus faecalis</i> -VRE	MRID 492603-09
<i>Staphylococcus aureus</i> -MRSA	MRID 492603-10
<i>Listeria monocytogenes</i>	MRID 492603-11
<i>Escherichia coli</i>	MRID 492603-20

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth. Antibiotic susceptibility testing demonstrated antibiotic resistance.

2.) The submitted efficacy data **does support** the use of the ready-to-use spray Clean Smart as a disinfectant against the following fungi on hard, non-porous surfaces with a 10-minute contact time:

<i>Trichophyton mentagrophytes</i>	MRID 492603-19
------------------------------------	----------------

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

3.) The submitted efficacy data **does support** the use of the ready-to-use spray Clean Smart as a disinfectant against the following viruses on hard, non-porous surfaces with a 1% organic soil load for a 10- minutes contact time:

Herpes Simplex Virus Type 1	MRID 492603-12
Herpes Simplex Virus Type 2	MRID 492603-13
Human Immunodeficiency Type 1	MRID 492603-14
Influenza A (H1N1) Virus	MRID 492603-15
Rhinovirus Type 37	MRID 492603-16
Human Coronavirus	MRID 492603-17
Respiratory Syncytial Virus	MRID 492603-18

Complete inactivation was demonstrated or at least a 3-log reduction in titer was shown beyond the cytotoxic level. Recoverable virus titers of at least  $10^4$  were achieved. Neutralization control demonstrated growth.

4.) The submitted efficacy data **does support** the use of the ready-to-use spray Clean Smart as a non-food contact sanitizer for use on hard, non-porous surfaces with bactericidal activity against the following microorganisms for a 5- minutes contact time:

<i>Staphylococcus aureus</i>	MRID 492603-21
<i>Enterobacter aerogenes</i>	MRID 492603-22

Results demonstrate a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Sterility controls did not show growth.

5.) The submitted efficacy data **does support** the use of the ready-to-use spray Clean Smart as a non-food contact sanitizer for use on hard, non-porous surfaces with bactericidal activity against the following microorganisms for a 30 seconds contact time:

<i>Streptococcus pneumonia</i>	MRID 492603-23
<i>Salmonella enterica</i>	MRID 492603-24
<i>Staphylococcus aureus</i> -MRSA	MRID 492603-25
<i>Enterococcus-faecalis</i> – VRE	MRID 492603-26
<i>Escherichia coli</i>	MRID 492603-27

Results demonstrate a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Sterility controls did not show growth. Antibiotic susceptibility testing demonstrated antibiotic resistance.

6.) The submitted efficacy data **does support** the use of the ready-to-use spray Clean Smart as a food contact sanitizer for use on hard, non-porous surfaces with bactericidal activity against the following microorganisms for a 1 minute contact time:

<i>Escherichia coli</i>	MRID 492603-28
<i>Staphylococcus aureus</i>	MRID 492603-29
<i>Salmonella enterica</i>	MRID 492603-30

Test results showed product concentrations equivalent in activity to 200 ppm of available chlorine. Neutralization confirmation testing and viability control showed positive growth of the microorganisms. Purity controls were reported as pure.

## VII. RECOMMENDATIONS:

1.) The product label proposes that the ready to use spray product Clean Smart is a disinfectant against the following microorganisms on hard, non-porous surfaces with a 10-minute contact time:

<i>Staphylococcus aureus</i>	(ATCC 6538)
<i>Salmonella enterica</i>	(ATCC 10708)

<i>Pseudomonas aeruginosa</i>	(ATCC 15442)
<i>Streptococcus pyogenes</i>	(ATCC 19615)
<i>Enterococcus faecalis</i> -VRE	(ATCC 51575)
<i>Staphylococcus aureus</i> -MRSA	(ATCC 33592)
<i>Listeria monocytogenes</i>	(ATCC 19117)
<i>Escherichia coli</i>	(ATCC 11229)

These claims are **acceptable** as they are supported by the submitted data.

2.) The product label proposes that the ready to use spray product Clean Smart is a disinfectant with fungicidal activity against the following organism on hard, non-porous surfaces with a 10-minute contact time:

<i>Trichophyton mentagrophytes</i>	(ATCC 9533)
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These claims are **acceptable** as they are supported by the submitted data.

3.) The product label proposes that the ready to use spray product Clean Smart is a disinfectant with virucidal activity against the following organisms on hard, non-porous surfaces with a 10-minute contact time:

Herpes Simplex Virus Type 1	(ATCC VR-733)
Herpes Simplex Virus Type 2	(ATCC VR-734)
Human Immunodeficiency Type 1	(Advanced Biotechnologies)
Influenza A (H1N1) Virus	(ATCC VR-1469)
Rhinovirus Type 37	(ATCC VR-1147)
Human Coronavirus	(ATCC VR-740)
Respiratory Syncytial Virus	(ATCC VR-26)

These claims are **acceptable** as they are supported by the submitted data.

4.) The product label proposes that the ready to use spray product Clean Smart is a non-food contact sanitizer against the following organisms on hard non-porous surfaces with a 5 minute contact time:

<i>Staphylococcus aureus</i>	(ATCC 6538)
<i>Enterobacter aerogenes</i>	(ATCC 13048)

These claims are **acceptable** as they are supported by the submitted data.

5.) The product label proposes that the ready to use spray product Clean Smart is a non-food contact sanitizer against the following organisms on hard non-porous surfaces with a 30 seconds contact time:

<i>Streptococcus pneumonia</i>	(ATCC 6305)
<i>Salmonella enterica</i>	(ATCC 10708)
<i>Staphylococcus aureus</i> -MRSA	(ATCC 33592)

*Enterococcus faecalis*- VRE  
*Escherichia coli*

(ATCC 51575)  
(ATCC 11229)

These claims are **acceptable** as they are supported by the submitted data.

6.) The product label proposes that the ready to use spray product Clean Smart is a food contact sanitizer against the following organisms on hard non-porous surfaces with a 1 minute contact time:

<i>Escherichia coli</i>	(ATCC 11229)
<i>Staphylococcus aureus</i>	(ATCC 6538)
<i>Salmonella enterica</i>	(ATCC 10708)

These claims are **acceptable** as they are supported by the submitted data.

#### **LABEL RECOMMENDATIONS:**

- Page 1- remove all hospital/healthcare sanitizer claims. Sanitizing claims are not acceptable for hospital use.
- Page 1- remove air disinfection claim. This is false and misleading. Data was not submitted to support this claim.
- Page 1- remove the term “Everywhere”. This is misleading. The product has been approved for use on hard non-porous surfaces which are not located everywhere.
- Under General Claims:
  - Remove all “quick” and all “fast” sanitization or disinfection references on the label as these claims are supported by 5 and 10 minute data, respectively.
  - Remove all references to use on produce and references to use on fruits and vegetables.
  - Remove the terms “everywhere” and “anywhere” from sanitization or disinfection statements as they imply product can be used on surfaces other than hard, non-porous surfaces.
- Under direction for use as a Sanitizer, rewrite “non-food surfaces” to state “non-food hard non-porous surfaces”
- Soak/immersion directions must be removed from label. The data submitted supports spray use only. Use dilution method was not used in the submitted studies to support soak/immersion claims.
- Page 6, remove the brackets around on hard, non-porous surfaces in the statement “Can reduce the spread of illness-causing (kitchen) bacteria (on hard, non-porous surfaces)”. In order to make this claim, “on hard, non-porous surfaces” must be stated.
- Page 6, remove “(Gently) (lightly)”. This is misleading. These claims have not been substantiated.
- Throughout the proposed label the word “bacteria” must be qualified with the approved microorganisms for non-food contact sanitization and disinfection on hard non-porous surfaces.
- Page 6, remove “without leaving a harmful chemical residue”. Data was not submitted to support this claim.

- Page 6, the surfaces in the statement “(Kills) (eliminates) (destroys) (removes) 99.9% of bacteria on commonly touched surfaces that can be transfer points for bacteria” must be qualified to state hard non-porous surfaces.
- Page 6, remove the following claims:  
 ““(Kills) (eliminates) (destroys) (removes) 99.9% of bacteria that (antibacterial) dish soap leaves behind”  
 ““(Kills) (eliminates) (destroys) (removes) 99.9% of bacteria that (antibacterial) dish soap can spread around”  
 ““(Kills) (eliminates) (destroys) (removes) 99.9% of bacteria, including *E. coli* and *Salmonella* that (antibacterial dish soap leaves behind and spread around”  
 These claims are misleading. It implies that antibacterial dish soap leads to the presence/existence of microorganisms.
- Page 7, rewrite the statement “Kills germs while it cleans” to state “Cleans while it kills germs”. The killing of germs requires a contact time whereas cleaning does not. Therefore, cleaning uses cannot promote killing of germs.
- Page 11-remove HAI and OSHA references. This implies endorsement.
- Page 11- revise cross-contamination claim to include “on hard non-porous surfaces”.
- Page 12- remove cleans and disinfects in one step. Disinfection requires a contact time whereas cleaning does not.
- Page 12- remove Appendix A reference and insert an appropriate organism reference list. Appendix A reference list was not included in the label.
- Page 12- remove the statement “[Product Name] [This Product] has demonstrated effectiveness against influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 [(formerly called swine flu)]”. This is misleading as data was not submitted to support the claim.
- Page 12- remove “Kills cold and flu viruses” or qualify the statement with the approved organisms associated with each claim.
- Page 12- the term “Virucidal” and “Fungicidal” must be qualified.
- Page 12- remove the statement “Immerse handling and restraining equipment such as leashes, muzzles, halters, or ropes”. This is misleading. Data was not submitted to support an immersion claim and the listed equipment are not considered hard non-porous surfaces.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: 485449

Nicola D. Cowen  
Senior Regulatory Consultant  
Exponent, Inc.  
Morris Corporate Center IV  
1150 Connecticut Ave., Suite 1100  
Washington DC 20036

MAY 19 2014

Subject: Product Name: Clean Smart  
EPA File Symbol: 89896-E  
Application Date: November 26, 2013  
EPA Receipt Date: November 27, 2013

Dear Ms. Cowen:

The Agency has completed its review of your application and has previously communicated to you on May 6, 2014 our pre-decisional determination that identified specific label changes that were necessary in order for the Agency to approve your application. At this time, there are label issues that have not yet been resolved. In accordance with Section 33(b)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended by the Pesticide Registration Improvement Extension Act of 2012, your application was assigned a decision review time. The Agency has reviewed the application and has determined that your product does not meet the criteria for registration under either FIFRA sec. 3(c)(5) or (7) without the specified label changes. This determination marks the end of the PRIA decision review period.

At this time you have three options:

- (a) Agree to all of the terms associated with the draft accepted label as revised by the Agency and request that it be issued as the accepted final Agency-stamped label; or
- (b) Do not agree to one or more of the terms of the draft accepted label as revised by the Agency and request additional time to resolve the difference(s); or
- (c) Withdraw the application without prejudice for subsequent resubmission, but forfeit the associated registration service fee.

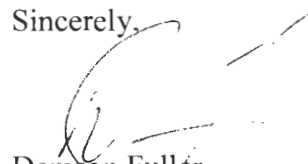
If you inform EPA that you have concerns as described under (b) above, you have up to 30 calendar days from the date of this letter to reach agreement with the Agency on the final version

of the label that the Agency will accept. If an agreement cannot be reached within those 30 days, EPA intends to proceed with denial of the application.

If you agree to all of the terms of the accepted label as described in (a) above, or if you and EPA resolve any differences as described in (b), you must submit a revised label to EPA. EPA will then provide you a stamped accepted final label within two (2) business days of receipt of your revised label.

Please respond to this letter by contacting me by telephone on 703-308-8062 or by e-mail at [fuller.demson@epa.com](mailto:fuller.demson@epa.com) with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read "Demson Fuller", is written over a horizontal line.

Demson Fuller,  
Product Manager 32  
Regulatory Management Branch II  
Antimicrobials Division 7510P



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

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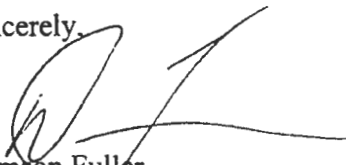
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Demson Fuller,  
Product Manager 32  
Regulatory Management Branch II  
Antimicrobials Division 7510P

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

**Office of Pesticide Programs**

**Antimicrobials Division (AD)**

March 26, 2014.

**MEMORANDUM**

**Subject:** Product Chemistry Review for EPA Reg # 89896-E.  
Product Name: **CleanSmart**  
DP #: 417077

**From:** Salvador Rodriguez, Chemist  
Product Science Branch, CT Team  
Antimicrobials Division (7510P)

**Thru:** Karen P. Hicks, CT Team Leader  
Product Science Branch  
Antimicrobials Division (7510P)

**To:** Demson Fuller.  
PM Team 32

**APPLICANT:** Simple Science, LLC

**Action code:** A540

**Due date:** 05/19/14

**Product Formulation from label**  
**Active Ingredient(s)**

**% by wt.**

Hypochlorous acid ..... 0.017

## BACKGROUND:

The registrant, Simple Science, LLC, has submitted the OPPTS Guideline, Series 830 Tables "A & B" to support the new registration for the disinfectant, integrated, non-food, end-use product, **CleanSmart**. The Product Chemistry Reviewer has reviewed the following documents:

- Confidential Statement of Formula (CSF), dated 11/26/13 for the basic and formulation.
- Cover & transmittal letter, dated 11/26/13. MRID #: 49260300
- Data matrix, dated 11/26/13.
- Label, dated 11/26/13.
- OPPTS Guideline, Series 830, Tables "A & B". Study titled: "Group A & B Product Chemistry for CleanSmart" MRID #s: 49260301, 49260302, 49260303 & 49260304.

## FINDINGS:

1. The CSF, dated 11/26/13, for the basic formulation is revised.
2. All the certified limits meet the EPA 40 CFR standard certified limits. The registrant has provided a justification letter, dated 11/18/13, for the use of wider certified limits for the active ingredient (AI).
3. The CSFs and the label have the same nominal.
4. The OPPTS Guidelines Group "A & B" product chemistry data requirements applicable to end-use products have been met. MRID #s: 49260301, 49260302, 49260303, & 49260304.
5. The registrant indicated that five pilot-scale batches for the product **CleanSmart** were selected for performing the Preliminary Analysis Study. Using the Enforcement Analytical Method, samples were analyzed and the mean of the five readings was used to express the weight % active ingredient (AI) in each sample.

The results are the following:

Lot #	%purity of Silver Nitrate
001	0.0166
002	0.0170
003	0.0168
004	0.0169
005	0.0169

6. The results of the accelerated (14 days) storage and of the test material have been determined. The study is in accordance with the requirements of the US EPA, Office of Prevention, Pesticides and Toxic Substances, Series 830: Products Properties Test Guidelines OPPTS 830.6317 & 830.6320.
7. After 14 days, no pitting, no thinning, no warping, no change in color, no cracks holes or mottling were noted for the commercial packaging material. Upon mechanical deformation, neither the container nor the closure cracked or split. In conclusion there was no significant change in the active ingredient content of the test material during the two years of storage.

Timepoint	Replicate 1	Replicate 2	Replicate 3
After 14 days at 54° C	0.017	0.0171	0.0170

#### CONCLUSIONS:

Product Science Branch of Antimicrobials Division finds the OPPTS Guideline, Series 830 group “A” and “B” product chemistry requirements for the integrated, non-food use, end-use products **CleanSmart** to be acceptable. The results of the five batch analysis and from the Storage Stability & Corrosion Characteristics essays are within the EPA standard certified limits.

## PRODUCT CHEMISTRY REVIEW

### I. CONFIDENTIAL STATEMENT OF FORMULA

#### a. Type of formulation and source registration:

- Non-integrated formulation system [ ]
- Are all TGAIs used registered? Yes [ ] No [ ]
- Integrated formulation system [X]
- If "ME-TOO," specify EPA Reg. No. of existing product: 87518-1

#### b. Clearance of inerts for non-food or food use:

The product is cleared for food use under 40 CFR §§180.940 and 180.950.  
Yes [ ] No [X]

#### c. Physical state of product:

*Liquid.*

#### d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No [ ]

#### e. The NCs and CLs are acceptable.

Yes [X] No [ ]

#### f. Active ingredient

<u>NC</u> (%)	<u>LCL</u> (%)	<u>UCL</u> (%)
------------------	-------------------	-------------------

Hypochlorous acid .....	0.017	0.010	0.017
-------------------------	-------	-------	-------

#### g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?  
Yes [X] No [ ] Not applicable [X]
- Have all impurities of  $\geq 0.1\%$  in the product been identified?  
Yes [ ] No [ ] Not applicable [X]

## II PRODUCT LABEL

a. The active ingredient statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- |  |         |        |
|--|---------|--------|
| • 10% or more of a petroleum distillate: | Yes [ ] | No [X] |
| • 1.0% or more of methyl alcohol:        | Yes [ ] | No [X] |
| • sodium nitrite at any level:           | Yes [ ] | No [X] |
| • a toxic List 1 inert at any level:     | Yes [ ] | No [X] |
| • arsenic in any form:                   | Yes [ ] | No [X] |

c. If “yes” to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes [ ] No [X]

**Table A:**  
**Product Chemistry (Series 830, Group A)**

<b>Data Requirements</b>	<b>Acceptance of Information</b>	<b>MRID No.</b>
830.1550 Product Identity <sup>1</sup>	A	49260301 49260302
830.1600 Description of Materials	A	49260301 49260302
830.1620 Production Process <sup>2</sup>	N/R	
830.1650 Formulation Process <sup>3</sup>	A	49260301 49260302
830.1670 Formation of Impurities <sup>4</sup>	A	49260301 49260302
830.1700 Preliminary Analysis <sup>5</sup>	A	49260302
830.1750 Certified Limits <sup>6</sup>	A	49260301 49260302
830.1800 Enforcement Analytical Method <sup>7</sup>	A	49260301 49260302
830.1900 Submittal of Samples	<i>[Samples are to be provided on a case-by-case basis for end-use products.]</i>	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

<sup>1</sup>See Confidential Appendix A for additional information.

<sup>2</sup>For MP/EP products produced by an integrated formulation system.

<sup>3</sup>For products from a TGAI or MP.

<sup>4</sup>May be waived unless actual/possible impurities are of toxicological concern.

<sup>5</sup>Five batch analysis required for products produced by an integrated formulation system.

<sup>6</sup>If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

<sup>7</sup>Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

**Table B:**  
**Physical and Chemical Characteristics (Series 830, Group B)**

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	N/R		49260303
830.6303 Physical State	A	Liquid	49260301 49260303
830.6304 Odor	A	Chlorine odor.	49260301 49260303
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NR		
830.6314 Oxidation/Reduction; Chemical Incompatibility	A	EPA has found this product, to be neither an oxidizer nor a reducer.	49260303
830.6315 Flammability/Flame Extension	A	No flash; Sample boiled at ~98° C	49260303
830.6316 Explodability	A	Contains no volatile materials.	
830.6317 Storage Stability	A	Accelerated Storage Stability has been provided.	49260304
830.6319 Miscibility <sup>1</sup>	A	Completely inorganic – not soluble with any organic solvent.	49260301
830.6320 Corrosion Characteristics	A	The product & container are stable.	49260304
830.6321 Dielectric Breakdown Voltage	A	The product is not intended for use in or around electrical equipment.	
830.7000 pH <sup>2</sup>	A	7 ± at 20° C	49260301 49260303
830.7050 UV/Visible Absorption	NR		
830.7100 Viscosity	N/R		
830.7200 Melting Point/Melting Range	N/R	The product is a liquid.	
830.7220 Boiling Point/Boiling Range	NR	100° C	49260302 49260303 49260304
830.7300 Density/Relative Density/Bulk Density	A	8.399 lbs/gal & 1.0012 g/cc	49260301 49260303
830.7370 Dissociation Constants in Water	N/R		

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7520 Particle size, fiber length, and diameter distribution.	N/R	.	
830.7840/830.7860 Water Solubility	NR		
830.7950 Vapor Pressure	NR		

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

---

\* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

<sup>1</sup>If product is an emulsifiable liquid

<sup>2</sup>If product is dispersible with water

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

Office of Pesticide Programs

**Antimicrobials Division (AD)**

March 26, 2014.

EPA Reg#: 89896-E		DP Barcode: 417077	
		Submission #: 944308	
Product name: <b>CleanSmart</b>		Registrant: Simple Science, LLC	
Reviewer's name: Salvador Rodriguez		AD/PSB/CTT- Product Chemistry	
Agency due date: 05/19/14		PSB received date: 01/10/14	
CTT received date: 01/10/14		Science due date: 04/19/14	
Formulation type: EUP			
Integrated system: <input checked="" type="checkbox"/>		Non integrated system: <input type="checkbox"/>	Food use: <input type="checkbox"/> Non food use: <input checked="" type="checkbox"/>
Action Code: A540		Date Completed: March 26, 2014	
<b>PC Code</b>	<b>CAS #</b>	<b>Active Ingredient Names</b>	<b>% wt (label)</b>
129054	7790-92-3	Hypochlorous Acid	0.017
$\text{H}-\text{O}-\text{Cl}$			
Test Lab: Simple Science Limited			
MRID(s): 49260301, 49260302, 49260303 & 49260304.			
Approver: Karen P. Hicks		Approved date: March 26, 2014.	
Guideline: OPPTS Guideline. Series 830 Groups "A & B"			
Comments:			

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460




United States  
Environmental Protection  
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**Office of Pesticide Programs**

**Antimicrobials Division (AD)**

March 26, 2014.

EPA Reg#: 89896-E		DP Barcode: 417077	
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Approver: Karen P. Hicks		Approved date: March 26, 2014.	
Guideline: OPPTS Guideline. Series 830 Groups "A & B"			
Comments:			

*Handwritten signature and date: 104/02/14*

## BACKGROUND:

The registrant, Simple Science, LLC, has submitted the OPPTS Guideline, Series 830 Tables “A & B” to support the new registration for the disinfectant, integrated, non-food, end-use product, **CleanSmart**. The Product Chemistry Reviewer has reviewed the following documents:

- Confidential Statement of Formula (CSF), dated 11/26/13 for the basic and formulation.
- Cover & transmittal letter, dated 11/26/13. MRID #: 49260300
- Data matrix, dated 11/26/13.
- Label, dated 11/26/13.
- OPPTS Guideline, Series 830, Tables “A & B”. Study titled: “Group A & B Product Chemistry for CleanSmart” MRID #s: 49260301, 49260302, 49260303 & 49260304.

## FINDINGS:

1. The CSF, dated 11/26/13, for the basic formulation is revised.
2. All the certified limits meet the EPA 40 CFR standard certified limits. The registrant has provided a justification letter, dated 11/18/13, for the use of wider certified limits for the active ingredient (AI).
3. The CSFs and the label have the same nominal.
4. The OPPTS Guidelines Group “A & B” product chemistry data requirements applicable to end-use products have been met. MRID #s: 49260301, 49260302, 49260303, & 49260304.
5. The registrant indicated that five pilot-scale batches for the product **CleanSmart** were selected for performing the Preliminary Analysis Study. Using the Enforcement Analytical Method, samples were analyzed and the mean of the five readings was used to express the weight % active ingredient (AI) in each sample.

The results are the following:

Lot #	%purity of Silver Nitrate
001	0.0166
002	0.0170
003	0.0168
004	0.0169
005	0.0169

6. The results of the accelerated (14 days) storage and of the test material have been determined. The study is in accordance with the requirements of the US EPA, Office of Prevention, Pesticides and Toxic Substances, Series 830: Products Properties Test Guidelines OPPTS 830.6317 & 830.6320.
7. After 14 days, no pitting, no thinning, no warping, no change in color, no cracks holes or mottling were noted for the commercial packaging material. Upon mechanical deformation, neither the container nor the closure cracked or split. In conclusion there was no significant change in the active ingredient content of the test material during the two years of storage.

Timepoint	Replicate 1	Replicate 2	Replicate 3
After 14 days at 54° C	0.017	0.0171	0.0170

## CONCLUSIONS:

Product Science Branch of Antimicrobials Division finds the OPPTS Guideline, Series 830 group “A” and “B” product chemistry requirements for the integrated, non-food use, end-use products **CleanSmart** to be acceptable. The results of the five batch analysis and from the Storage Stability & Corrosion Characteristics essays are within the EPA standard certified limits.

## PRODUCT CHEMISTRY REVIEW

### I. CONFIDENTIAL STATEMENT OF FORMULA

#### a. Type of formulation and source registration:

- Non-integrated formulation system [ ]
- Are all TGAIs used registered? Yes [ ]      No [ ]
- Integrated formulation system [X]
- If “ME-TOO,” specify EPA Reg. No. of existing product: 87518-1

#### b. Clearance of inerts for non-food or food use:

The product is cleared for food use under 40 CFR §§180.940 and 180.950.  
Yes [ ]      No [X]

#### c. Physical state of product:

*Liquid.*

#### d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X]      No [ ]

#### e. The NCs and CLs are acceptable.

Yes [X]      No [ ]

#### f. Active ingredient

	<u>NC</u> (%)	<u>LCL</u> (%)	<u>UCL</u> (%)
--	------------------	-------------------	-------------------

Hypochlorous acid .....	0.017	0.010	0.017
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#### g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?  
Yes [X]      No [ ]      Not applicable [X]
- Have all impurities of  $\geq 0.1\%$  in the product been identified?  
Yes [ ]      No [ ]      Not applicable [X]

## II PRODUCT LABEL

a. The active ingredient statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes ☒ No ☐

b. The formula contains one of the following:

- |  |                              |  |
|--|------------------------------|--|
| • 10% or more of a petroleum distillate: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • 1.0% or more of methyl alcohol:        | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • sodium nitrite at any level:           | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • a toxic List I inert at any level:     | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • arsenic in any form:                   | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |

c. If “yes” to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes ☐ No ☐ Not applicable ☒

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.  
Yes ☐ No ☐ Not applicable ☒

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.  
Yes ☒ No ☐

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).  
Yes ☐ No ☒

**Table A:**  
**Product Chemistry (Series 830, Group A)**

<b>Data Requirements</b>	<b>Acceptance of Information</b>	<b>MRID No.</b>
830.1550 Product Identity <sup>1</sup>	A	49260301 49260302
830.1600 Description of Materials	A	49260301 49260302
830.1620 Production Process <sup>2</sup>	N/R	
830.1650 Formulation Process <sup>3</sup>	A	49260301 49260302
830.1670 Formation of Impurities <sup>4</sup>	A	49260301 49260302
830.1700 Preliminary Analysis <sup>5</sup>	A	49260302
830.1750 Certified Limits <sup>6</sup>	A	49260301 49260302
830.1800 Enforcement Analytical Method <sup>7</sup>	A	49260301 49260302
830.1900 Submittal of Samples	<i>[Samples are to be provided on a case-by-case basis for end-use products.]</i>	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

<sup>1</sup>See Confidential Appendix A for additional information.

<sup>2</sup>For MP/EP products produced by an integrated formulation system.

<sup>3</sup>For products from a TGAI or MP.

<sup>4</sup>May be waived unless actual/possible impurities are of toxicological concern.

<sup>5</sup>Five batch analysis required for products produced by an integrated formulation system.

<sup>6</sup>If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

<sup>7</sup>Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

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**Physical and Chemical Characteristics (Series 830, Group B)**

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
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830.6320 Corrosion Characteristics	A	The product & container are stable.	49260304
830.6321 Dielectric Breakdown Voltage	A	The product is not intended for use in or around electrical equipment.	
830.7000 pH <sup>2</sup>	A	7 ± at 20° C	49260301 49260303
830.7050 UV/Visible Absorption	NR		
830.7100 Viscosity	N/R		
830.7200 Melting Point/Melting Range	N/R	The product is a liquid.	
830.7220 Boiling Point/Boiling Range	NR	100° C	49260302 49260303 49260304
830.7300 Density/Relative Density/Bulk Density	A	8.399 lbs/gal & 1.0012 g/cc	49260301 49260303
830.7370 Dissociation Constants in Water	N/R		

<b>Physical/Chemical Properties*</b>	<b>Acceptance of Data</b>	<b>Value or Qualitative Description</b>	<b>MRID No.</b>
830.7520 Particle size, fiber length, and diameter distribution.	N/R	.	
830.7840/830.7860 Water Solubility	NR		
830.7950 Vapor Pressure	NR		

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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\* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

<sup>1</sup>If product is an emulsifiable liquid

<sup>2</sup>If product is dispersible with water

# DATA PACKAGE BEAN SHEET

Date: 02-Jan-2014

Page 1 of 1

Decision #: 485449

DP #: (417077)

PRIA

Parent DP #:

Submission #: 944308

E-Sub #: 5075

## \*\*\* Registration Information \*\*\*

### Registration: 89896-E - CleanSmart

Company: 89896 - SIMPLE SCIENCE, LLC

Risk Manager: RM 32 - Demson Fuller - (703) 308-8062 Room# PY1 S-8834

Risk Manager Reviewer: Demson Fuller DFULLE02

Sent Date:

PRIA Due Date: 19-May-2014

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A540) NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Ingredients: 129054, Hypochlorous Acid(.017%)

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 02-Jan-2014

Due Back:

DP Ingredient: 129054, Hypochlorous Acid

DP Title: Product Chemistry

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

### Assigned To

Organization: AD / PSB

Team Name: CTT

Reviewer Name:

Contractor Name:

Date In

Date Out

Last Possible Science Due Date: 19-Apr-2014

Science Due Date:

Sub Data Package Due Date:

## \*\*\* Studies Sent for Review \*\*\*

No Studies

## \*\*\* Additional Data Package for this Decision \*\*\*

Can be printed on its own page

## \*\*\* Data Package Instructions \*\*\*

Please conduct and conclude the technical screen for this submission by 1/30/14.

This was submitted as an e-submission. In addition, the following documents are included:

- Cover Letter
- Label
- Data Matrix

Please review the data matrix and cover letter to see what data (MRID#s) have been submitted to support this registration. The CSF or any other needed information can be obtained from documentum.

If you have any questions, please feel free to contact David Liem. Thank you.

Demson

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

Office of Pesticide Programs

February 14, 2011

MEMORANDUM

SUBJECT: Acute Toxicity Review for EPA File Symbol: 87518-R  
Product Name: Hsp<sub>2</sub>O  
DP Barcode: 383728

FROM: Earl Goad, Biologist  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

TO: Wanda Henson (acting PM#32)/Tom Luminello  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Applicant: HSP USA, LLC

PRODUCT FORMULATION FROM LABEL:

<u>PC Codes</u>	<u>Active Ingredient(s):</u>	<u>% by wt.</u>
129054	Hypochlorous Acid	0.018
	<u>Other Ingredient(s):</u>	<u>99.982</u>
	Total:	100.000

## I) BACKGROUND:

HSP USA, LLC, initially applied for their registration of Hsp<sub>20</sub> citing the acute toxicity data which had previously been submitted for another product (Oculus Microcyn, EPA Registration Number 81206-1). The citation of this data as a means of bridging the acute toxicity profile from that registered product to this new application was found acceptable in an acute toxicity review dated August 3, 2010.

However there were two issues identified that disfavored the acceptability of such bridging. The registration of the product cited had been cancelled. Also, the new registrant was unable to contact the parties with Oculus in order to negotiate compensation for the use of their supporting study data.

As a result the registrant changed their means of support from citation/bridging of the Oculus study data to instead provide a justification to waive the requirement of product specific acute toxicity on the basis of a rationale of very low toxicity which would be associated with such a dilute product.

Subsequently it has been determined that there is sufficient justification to let the earlier decision of using the Oculus acute toxicity profile to prevail.

## II) FINDINGS

- The applicability of Oculus acute toxicity for the purpose of citation/bridging to this product should rest entirely upon the substantial similarity of the two products.
- Oculus acute toxicity study data was found acceptable. That acceptability is not diminished by the withdrawal or cancellation of that product.
- The inability of the new registrant to contact Oculus to negotiate compensation does not enter in to the applicability for data bridging. The Agency only requires that the new registrant provide the offer of data compensation. Any further arrangements between the registrant and the data provider are out of the Agencies hands.
- Additionally CTT understands that the low concentration of hypochlorous acid in this product is close to the tolerance exemption for food contact surface sanitization usage. There is ample evidence of the low acute toxicity of end use solutions (hypochlorite/hypochlorous) of approximately 200 ppm. This product is a ready to use product at close to neutral pH – avoiding any exposure to the much more corrosive (alkaline) bleach products that would normally be used to prepare such use dilutions.

## III) RECOMMENDATIONS:

- A. CTT recommends that the data which supports the acute toxicity profile for this product be cited/bridged from the existing approved acute toxicity profile of 81206-1 Oculus Microcyn.
- B. The Agency has already received the offer to pay from the registrant. It is up to the registrant to pursue data compensation negotiations.

IV) The acute toxicity profile for EPA File Symbol: 87518-R Hsp20 is currently:\*\*

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	462324-05	IV	Bridged/Cited
Acute Dermal Toxicity	462324-06	IV	Bridged/Cited
Acute Inhalation Toxicity	462324-07	IV	Bridged/Cited
Primary Eye Irritation	464537-01	IV	Bridged/Cited
Primary Skin Irritation	464537-02	IV	Bridged/Cited
Dermal Sensitization	462324-10	Non-Sensitizer	Bridged/Cited

\*\* Cited from: EPA Registration Number 81206-1 "Oculus Microcyn"

V) LABELING:

- A. According to Chapter 7 of the Current Label Review Manual no signal word would be required if all five routes of exposure are graded as category IV.
- B. Due to the cited/bridged acute toxicity profile, no precautionary statements or first aid statements are required.

Note: Should the registrant wish to provide a signal word, precautionary and/or first aid labeling they may do so provided the labeling does not represent a hazard greater than "CAUTION".

- C. The studies being cited were performed under the guideline conditions of acute (short term) exposure to that product. The registrant may wish to consider caution level labeling or specifying personal protective equipment for those users and use patterns which might present a higher likelihood of prolonged or chronic exposure which could prove irritating to eye and skin.





UNITED STATES ENVIRONMENTAL PROTECTION  
AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

January 15, 2014

MEMORANDUM

SUBJECT: Acute Toxicity Review for EPA Reg. No.: 89896-E  
DP Barcode: D417076

FROM: Chris Jiang, Chemist  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

*Chris Jiang*  
11/15/14  
*K. P. H.*

THRU: Karen Hicks, Team Leader  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

TO: Jacqueline Campbell-McFarlane PM 32  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Applicant: Simple Science, LLC

FORMULATION FROM LABEL:

Active Ingredient(s):

Hypochlorous acid

Other Ingredient(s):

Total:

% by wt.

0.017

99.983

100.0000

**BACKGROUND:** The registrant has submitted an acute toxicity package to register this non-integrated end-use product. The package contains a label, a Confidential Statement of Formula for the basic formulation, a data matrix, and a cover letter. The registrant wishes to cite data from 87518-1 to cover the acute toxicity requirements for this product.

**FINDINGS:**

1. The current acute toxicity profile for 87518-1 is:

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	46232405	IV	Cited
Acute Dermal Toxicity	46232406	IV	Cited
Acute Inhalation Toxicity	46232407	IV	Cited
Primary Eye Irritation	46453701	IV	Cited
Primary Skin Irritation	46453702	IV	Cited
Dermal Sensitization	46232410	Nonsensitizer	Cited

2. The registrant may cite the data for 87518-1 to cover the acute toxicity requirements for 89896-E.

**LABELING**

1. The optional signal word is **CAUTION**.
2. No precautionary statements are required.
3. No first aid statements are required.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

**Office of Pesticide Programs**

**Antimicrobials Division (AD)**

March 26, 2014.

**MEMORANDUM**

**Subject:** Product Chemistry Review for EPA Reg # 89896-E.  
Product Name: **CleanSmart**  
DP #: 417077

**From:** Salvador Rodriguez, Chemist  
Product Science Branch, CT Team  
Antimicrobials Division (7510P)

**Thru:** Karen P. Hicks, CT Team Leader  
Product Science Branch  
Antimicrobials Division (7510P)

**To:** Demson Fuller.  
PM Team 32

**APPLICANT:** Simple Science, LLC

**Action code:** A540

**Due date:** 05/19/14

**Product Formulation from label**  
**Active Ingredient(s)**

**% by wt.**

Hypochlorous acid ..... 0.017



## TRANSMITTAL DOCUMENT

### **NAME AND ADDRESS OF SUBMITTER:**

Simple Science Limited  
530 N 3rd St, #310  
Minneapolis, MN 55401

### **CONTACT PERSON (Return to):**

James Messina  
Authorized Representative of  
Simple Science Limited  
Exponent  
1150 Connecticut Ave, N.W.  
Suite 1100  
Washington, DC 20036

### **REGULATORY ACTION SUPPORTED BY THIS PACKAGE:**

This submission is prepared to support a new end-use product (PRIA A540) for:

CleanSmart, EPA Reg. No. 89896-~~RC~~

### **SUBMITTAL DATE:**

November 26, 2013

Volume	Study Title	MRID No.
1	Administrative Materials	49260300
2	Group A Product Chemistry For Simple Science Limited's CleanSmart; DeGroot S., (2013). EPA Guidelines OPPTS 830.1550; 830.1600; 830.1620; 830.1650; 830.1670; 830.1750; 830.1800.	49260301
3	CleanSmart: Preliminary Analysis; Sinning D.J., (2013). EPA Guideline OPPTS 830.1700.	49260302
4	Physical Chemical Characteristics of CleanSmart: Color, Physical State, Odor, Oxidation/Reduction, Flammability, pH, Viscosity and Relative Density; Sinning D.J., (2013). EPA Guideline OPPTS 830.6302; 830.6303; 830.6304; 830.6314; 830.6315; 830.7000; 830.7100; 830.7300.	49260303

Volume	Study Title	MRID No.
5	Physical and Chemical Characteristics of CleanSmart: Storage Stability and Corrosion Characteristics; Sinning D.J., (2013). EPA OPPTS 830.6317 and 830.6320.	49260304
6	AOAC Germicidal Spray Method: <i>Staphylococcus aureus</i> (ATCC 6538); Schroeder G., (2013). EPA OPPTS 810.2200.	49260305
7	AOAC Germicidal Spray Method: <i>Salmonella enterica</i> (ATCC 10708); Schroeder G., (2013). EPA OPPTS 810.2200.	49260306
8	AOAC Germicidal Spray Method: <i>Pseudomonas aeruginosa</i> (ATCC 15442); Schroeder G., (2013). EPA OPPTS 810.2200.	49260307
9	AOAC Germicidal Spray Method: <i>Streptococcus pyogenes</i> (ATCC 19615); Schroeder G., (2013). EPA OPPTS 810.2200.	49260308
10	AOAC Germicidal Spray Method: <i>Enterococcus faecalis</i> (ATCC 51575); Schroeder G., (2013). EPA OPPTS 810.2200.	49260309
11	AOAC Germicidal Spray Method: Methicillin Resistant <i>Staphylococcus aureus</i> (ATCC 33592); Schroeder G., (2013). EPA OPPTS 810.2200.	49260310
12	AOAC Germicidal Spray Method: <i>Listeria monocytogenes</i> (ATCC 19117); Schroeder G., (2013). EPA OPPTS 810.2200.	49260311
13	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Herpes simplex virus type 1; Conway S., (2013). EPA OPPTS 810.2200.	49260312
14	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Herpes simplex virus type 2; Conway S., (2013). EPA OPPTS 810.2200.	49260313
15	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Human Immunodeficiency Virus type 1; Miller J.M., (2013). EPA OPPTS 810.2200.	49260314
16	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Influenza A (H1N1) virus; Conway S., (2013). EPA OPPTS 810.2200.	49260315
17	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Rhinovirus type 37; Conway S., (2013). EPA OPPTS 810.2200.	49260316
18	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Human Coronavirus; Conway S., (2013). EPA OPPTS 810.2200.	49260317
19	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Respiratory syncytial virus (RSV); Conway S., (2013). EPA OPPTS 810.2200.	49260318
20	Fungicidal Germicidal Spray Method <i>Trichophyton mentagrophytes</i> (ATCC 9533); Stemper A., (2013). EPA OPPTS 810.2200.	49260319
21	AOAC Germicidal Spray Method: <i>Escherichia coli</i> (ATCC 11229); Sathe M., (2013). EPA OPPTS 810.2200.	49260320

Volume	Study Title	MRID No.
22	Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces: <i>Staphylococcus aureus</i> (ATCC 6538); Schroeder G., (2013). EPA OPPTS 810.2300.	49260321
23	Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces: <i>Enterobacter aerogenes</i> (ATCC 13048); Schroeder G., (2013). EPA OPPTS 810.2300.	49260322
24	Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces: <i>Streptococcus pneumoniae</i> (ATCC 6305); Schroeder G., (2013). EPA OPPTS 810.2300.	49260323
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31	AOAC Available Chlorine in Disinfectants: <i>Escherichia coli</i> (ATCC 11229); Ruhme J., (2013). EPA OPPTS 810.2300.	49260330



**Liem, David**

---

**From:** Fuller, Demson  
**Sent:** Tuesday, February 18, 2014 5:29 PM  
**To:** Nicola Cowen  
**Cc:** Liem, David  
**Subject:** RE: SIMPLE SCIENCE, LLC - EPA Reg. # 89896-E - REVISED

Hi Niki,

The product chemistry technical screen has passed.

I will touch base with you shortly on the acute toxicity.

Let us know if you have any other questions.

Demson

**From:** Nicola Cowen [mailto:ncowen@exponent.com]  
**Sent:** Tuesday, February 18, 2014 1:25 PM  
**To:** Fuller, Demson  
**Cc:** Liem, David  
**Subject:** RE: SIMPLE SCIENCE, LLC - EPA Reg. # 89896-E - REVISED

Hi Demson,

Per our discussion, following the meeting this morning, please provide me with the assessment/conclusions of acute toxicity and product chemistry data for the 45 day technical review. Thank you.

Best regards,

Niki

**From:** Fuller, Demson [mailto:Fuller.Demson@epa.gov]  
**Sent:** Wednesday, February 12, 2014 7:51 PM  
**To:** Nicola Cowen  
**Cc:** Liem, David  
**Subject:** RE: SIMPLE SCIENCE, LLC - EPA Reg. # 89896-E - REVISED

Hi Nicola,

I wanted to touch base with you in regards to your earlier inquiry. The 45 day did pass for the efficacy. I do need to follow up with you in regards to acute toxicity and product chemistry. Also, you can contact David Liem if you have any questions. He is cc'ed on this message.

Thanks

Demson

**From:** Nicola Cowen [mailto:ncowen@exponent.com]  
**Sent:** Wednesday, February 05, 2014 1:51 PM

**To:** Fuller, Demson  
**Subject:** RE: SIMPLE SCIENCE, LLC - EPA Reg. # 89896-E - REVISED

Demson,

I have not received a letter for the 45 day technical screen review and was wondering if you could provide me with an update on the status of the Simple Science submission package. Thank you.

Best regards,

Niki

**From:** Fuller, Demson [<mailto:Fuller.Demson@epa.gov>]  
**Sent:** Tuesday, December 31, 2013 12:30 PM  
**To:** Nicola Cowen  
**Subject:** RE: SIMPLE SCIENCE, LLC - EPA Reg. # 89896-E - REVISED

Hi Nicola,

Sorry for the delay in this message. The due date for this action is 5/29/14. It is currently out of the 21 day technical screen and is going thru the 45 day technical screen review.

Let me know if you have any other questions. And happy new year!

Demson

**From:** Nicola Cowen [<mailto:ncowen@exponent.com>]  
**Sent:** Monday, December 23, 2013 12:28 PM  
**To:** Fuller, Demson  
**Subject:** FW: SIMPLE SCIENCE, LLC - EPA Reg. # 89896-E - REVISED

Hi Demson,

Could you please give me the PRIA due date for the Simple Science, LLC (EPA Reg. # 89896-E) application package? Is the submission currently undergoing the 21 day screen? Thank you.

Best regards,

Niki

**From:** Green, Christopher [<mailto:Green.Christopher@epa.gov>]  
**Sent:** Monday, December 23, 2013 12:01 PM  
**To:** Nicola Cowen  
**Subject:** RE: SIMPLE SCIENCE, LLC - EPA Reg. # 89896-E - REVISED

The request was approved on December 18, 2013, and you will receive the approval letter by mail once it's signed.

**From:** Nicola Cowen [<mailto:ncowen@exponent.com>]  
**Sent:** Friday, December 20, 2013 9:10 AM  
**To:** Green, Christopher  
**Cc:** Seth DeGroot ([seth.degroot@sourcececa.com](mailto:seth.degroot@sourcececa.com)); Patrick O'Shaughnessy ([patrick.oshaughnessy@sourcececa.com](mailto:patrick.oshaughnessy@sourcececa.com))  
**Subject:** RE: SIMPLE SCIENCE, LLC - EPA Reg. # 89896-E - REVISED

Chris,

I am assuming you do not need any additional information for this small business waiver. When can we expect a letter of acceptance? Thank you.

Have a wonderful holiday!

Best regards,

Niki

**Nicola D. Cowen, MSc.**

Senior Regulatory Consultant

**E<sup>x</sup>ponent<sup>®</sup>, Inc**

1150 Connecticut Avenue, Suite 1100 | Washington, DC 20036 |

p: 202-772-4919 | e-mail: [ncowen@exponent.com](mailto:ncowen@exponent.com) | web: [www.exponent.com](http://www.exponent.com)

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**From:** Nicola Cowen

**Sent:** Friday, December 13, 2013 12:41 PM

**To:** 'Green, Christopher'

**Cc:** Seth DeGroot ([seth.degroot@sourceeca.com](mailto:seth.degroot@sourceeca.com))

**Subject:** RE: SIMPLE SCIENCE, LLC - EPA Reg. # 89896-E - REVISED

Chris,

Please see attached the Certificate of Formation for the OS Group, LLC and the Certification of Incorporation for Simple Science, Ltd (formerly Ressehold Ltd). Neither OS Group, nor Simple Science LLC, were in business in 2010 or 2011. This information is available in the OS Group Certification of Formation (see attached).

Please let me know if you have any other questions or need additional information. I hope you have a nice weekend.

Best regards,

Niki

**From:** Green, Christopher [<mailto:Green.Christopher@epa.gov>]

**Sent:** Friday, December 13, 2013 10:30 AM

**To:** Nicola Cowen

**Subject:** FW: SIMPLE SCIENCE, LLC - EPA Reg. # 89896-E - REVISED

Nicola,

So the "OS Group LLC" was in business in 2010 & 2011? Did they have revenue from the sale or distribution of pesticides in 2010 & 2011? If so, then we still need the revenue statements for 2010 & 2011 for the OS Group LLC because the only thing the applicant did was change the name of the company. See note below from our website.

**\* I'd like to request a fee waiver for small business, but I am a newly formed start-up company. What supporting documentation should I submit?**

The Agency will consider these situations on a case-by-case basis. To the extent possible, the applicant should provide the same information as other applicants regarding the number of employees and affiliates. **The applicant should disclose whether the ownership or management of the new entity had control over other entities with gross global revenue from pesticides in the prior applicable three-year period. The Agency will not grant a waiver if it determines that the entity submitting the application has been formed or manipulated primarily for the purpose of qualifying for the waiver.**

**From:** Green, Christopher  
**Sent:** Friday, December 13, 2013 10:22 AM  
**To:** 'Nicola Cowen'  
**Subject:** RE: SIMPLE SCIENCE, LLC - EPA Reg. # 89896-E - REVISED

Thanks for explaining the meaning of "OS Group, LLC", however, this does not show when Simple Science Limited was formed. Your statements indicated that both entities did not exist in 2010 & 2011, therefore, I'm requesting the official incorporation documents showing when Simple Science Limited was formed. Thanks.

**From:** Nicola Cowen [<mailto:ncowen@exponent.com>]  
**Sent:** Thursday, December 12, 2013 2:34 PM  
**To:** Green, Christopher  
**Cc:** Seth DeGroot ([seth.degroot@sourceeca.com](mailto:seth.degroot@sourceeca.com)); James Messina  
**Subject:** RE: SIMPLE SCIENCE, LLC - EPA Reg. # 89896-E - REVISED

Chris,

I have attached the following documents to answer your questions:

- 1) Certificate of Amendment - Name change 'OS Group, LLC' to 'Simple Science, LLC'
- 2) Simple Science EIN Assignment Letter

The reason you see the name 'OS Group, LLC' on the 941 is because Simple Sciences' accounting department was in the process of switching the name and EIN number in their accounting system at the time the 941 was filed, so the 941 was filed under the old name/EIN.

Best regards,

Niki

**From:** Green, Christopher [<mailto:Green.Christopher@epa.gov>]  
**Sent:** Wednesday, December 11, 2013 4:48 PM  
**To:** Nicola Cowen  
**Subject:** RE: SIMPLE SCIENCE, LLC - EPA Reg. # 89896-E - REVISED

Nicola,

Thanks for the documentation. A couple more questions.

1. What does "**OS Group LLC**" refer to on the provided form 941 showing the number of employees? The "Employer Identification Number does not match the number listed on the tax return for Simple Science, LLC. We need the number of employees for the applicant.
2. Can you provide the official incorporation documents showing when both entities were formed?

**From:** Nicola Cowen [<mailto:ncowen@exponent.com>]  
**Sent:** Wednesday, December 11, 2013 3:52 PM  
**To:** Green, Christopher  
**Cc:** Seth DeGroot ([seth.degroot@sourceeca.com](mailto:seth.degroot@sourceeca.com)); James Messina  
**Subject:** RE: SIMPLE SCIENCE, LLC - EPA Reg. # 89896-E

Chris,

Please see attached the additional information you requested in your email below. If you have any additional questions or require additional clarification/information, please feel free to contact me. Thank you.

Best regards,

Niki  
Nicola D. Cowen, MSc.  
Senior Regulatory Consultant  
**E<sup>x</sup>ponent<sup>®</sup>, Inc**  
1150 Connecticut Avenue, Suite 1100 | Washington, DC 20036 |  
p: 202-772-4919 | e-mail: [ncowen@exponent.com](mailto:ncowen@exponent.com) | web: [www.exponent.com](http://www.exponent.com)

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**From:** Green, Christopher [<mailto:Green.Christopher@epa.gov>]  
**Sent:** Thursday, December 05, 2013 1:18 PM  
**To:** Nicola Cowen  
**Cc:** [seth.degroot@sourceeca.com](mailto:seth.degroot@sourceeca.com)  
**Subject:** SIMPLE SCIENCE, LLC - EPA Reg. # 89896-E

Nicola,

The Office of Pesticide Programs has received your request for a 75% Small Business Fee Waiver. During the administrative screen it was determined additional information is needed. Please provide the following:

1. Do any stakeholders with a controlling interest or majority shareholder in the applicant or any parent entity also directly or indirectly control or have the ability to directly or indirectly control any other entity with global revenue from the sale or distribution of pesticides?
2. Confirm the authority of "Seth DeGroot", to sign the certification form on behalf of the applicant. The agency requires the certification form to be signed by a "responsible officer" of the applicant's entity.
3. Does the affiliate "Simple Science Limited" have revenue from the sale or distribution of pesticides?

FYI, affiliates include direct and indirect subsidiary and parent entities of the applicant as well as entities that are controlled directly or indirectly by the owner(s) or any parent entity of the applicant. In addition, two unrelated entities are affiliates if they are both owned or controlled by the same entity or person. Specifically, business entities are affiliates of each other if, directly or indirectly, either entity controls or has the power to control the other entity, or a third entity controls or has the power to control both entities. Indicia of control include interlocking management or ownership, identity of interests among family members, shared facilities and equipment, and common use of employees. Accordingly, control is not limited to voting control over another entity.

FYI, global gross revenue from pesticides (as defined in FIFRA and the implementing regulations) is not limited to revenue from pesticides for which the applicant is the registrant but includes all revenue from the distribution or sale by the applicant or any of its affiliates of a substance (or mixture of substances) that is intended for a pesticidal purpose or is advertised as having pesticidal purpose, either in the United States or abroad, even if (i) the applicant is not the registrant and (ii) the substance or device is not registered in the United States. Thus, global gross revenue from pesticides includes revenue from pesticides that are not currently registered in the United States. Global gross revenue from pesticides also includes all revenue from the sale or distribution of so-called "Section 25(b)" exempt pesticides. Global gross revenue from pesticides does not, however, include revenue from devices that are sold separately from a pesticide.

For all inert manufacturers, "global gross revenue from pesticides" includes all revenue from the distribution or sale by the applicant or any of its affiliates of an inert ingredient for formulation into a pesticide either in the United States or abroad. Global gross revenue from pesticides also includes all revenue from the sale or distribution of inert ingredients for so-called "Section 25(b)" exempt pesticides.

If you are both a registrant and an inert manufacturer and you request a small business waiver, "global gross revenue from pesticides" includes revenue from pesticide sales as well as the inert sales that go into the formulation of pesticides.

FYI, a pesticide is any substance (or mixture of substances) intended for a pesticidal purpose, *i.e.*, use for the purpose of preventing, destroying, repelling, or mitigating any pest or use as a plant regulator, defoliant, or desiccant. A substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if:

- (a) The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise):
  - (1) That the substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or
  - (2) That the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide; or
- (b) The substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than (1) use for pesticidal purpose (by itself or in combination with any other substance), (2) use for manufacture of a pesticide; or
- (c) The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.

4. Revenue statements for the applicant, parent and affiliates, showing annual global gross revenue from pesticides for each of the **three** most recent completed tax years or fiscal years, 2010, 2011 & 2012. This may include the **signed first page only** of tax returns filed with the Internal Revenue Service such as IRS form 1120, 1120S, or 1065, as appropriate, or copies of **relevant pages** from **audited** financial statements, (Relevant pages include the cover sheet showing who did the audit & pages showing the global gross sales revenue). If 2012 is not yet available, please provide an estimate of the global gross sales for 2012.

5. Confirm that the revenue statements include all **global/worldwide (not only U.S.)** gross pesticide revenue.

6. Does the applicant have a website?

### **Guidance On How To Request Small Business Fee Waivers:**

<http://www.epa.gov/pesticides/fees/questions/waivers.htm>

Thank you for your cooperation in this matter, and should you have any questions, please do not hesitate to contact me.

Chris Green  
Information Management Specialist  
US Environmental Protection Agency  
Phone: (703) 347-0367  
Fax: (703) 305-7670  
[Green.Christopher@epa.gov](mailto:Green.Christopher@epa.gov)



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Suite 1100  
Washington DC, 20036  
Telephone: 202-772-4900  
Facsimile: 202-772-4979  
www.exponent.com

## TRANSMITTAL DOCUMENT

### **NAME AND ADDRESS OF SUBMITTER:**

Simple Science Limited  
530 N 3rd St, #310  
Minneapolis, MN 55401

### **CONTACT PERSON (Return to):**

James Messina  
Authorized Representative of  
Simple Science Limited  
Exponent  
1150 Connecticut Ave, N.W.  
Suite 1100  
Washington, DC 20036

### **REGULATORY ACTION SUPPORTED BY THIS PACKAGE:**

This submission is prepared to support a new end-use product (PRIA A540) for:

CleanSmart, EPA Reg. No. 89896-~~RT~~

### **SUBMITTAL DATE:**

November 26, 2013

Volume	Study Title	MRID No.
1	Administrative Materials	49260300
2	Group A Product Chemistry For Simple Science Limited's CleanSmart; DeGroot S., (2013). EPA Guidelines OPPTS 830.1550; 830.1600; 830.1620; 830.1650; 830.1670; 830.1750; 830.1800.	49260301
3	CleanSmart: Preliminary Analysis; Sinning D.J., (2013). EPA Guideline OPPTS 830.1700.	49260302
4	Physical Chemical Characteristics of CleanSmart: Color, Physical State, Odor, Oxidation/Reduction, Flammability, pH, Viscosity and Relative Density; Sinning D.J., (2013). EPA Guideline OPPTS 830.6302; 830.6303; 830.6304; 830.6314; 830.6315; 830.7000; 830.7100; 830.7300.	49260303

Volume	Study Title	MRID No.
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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1200 Pennsylvania Avenue, N.W.

Washington, DC 20460

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## Data Matrix

Date: Draft November 26, 2013

EPA Reg. No./File Symbol: 89896-R

Page 1 of 3

Applicant's/Registrant's Name and Address: Simple Science Limited  
530 N 3<sup>rd</sup> St, #310  
Minneapolis, MN 55401

Product Name:

CleanSmart

Ingredients: Hypochlorous acid (CAS# 7790-92-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
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## § 158.2210: Product Chemistry Data Requirements

830.1550	Product identity and composition	49260301	Simple Science Limited	OWN	Volume 2
830.1600	Description of materials used to produce the product	49260301	Simple Science Limited	OWN	Volume 2
830.1620	Description of production process	49260301	Simple Science Limited	OWN	Volume 2
830.1650	Description of formulation process	49260301	Simple Science Limited	OWN	Volume 2
830.1670	Discussion of formation of impurities	49260301	Simple Science Limited	OWN	Volume 2
830.1700	Preliminary analysis	49260302	Simple Science Limited	OWN	Volume 3
830.1750	Certified limits	49260301	Simple Science Limited	OWN	Volume 2
830.1800	Enforcement analytical method	49260301	Simple Science Limited	OWN	Volume 2
830.1900	Submittal of samples	49260301	Simple Science Limited	OWN	Volume 2

## Physical and Chemical Properties

830.6302	Color	49260303	Simple Science Limited	OWN	Volume 4
830.6303	Physical state	49260303	Simple Science Limited	OWN	Volume 4
830.6304	Odor	49260303	Simple Science Limited	OWN	Volume 4
830.6313	Stability (normal/elevated temperatures, metals and ions)		Not expected to come into contact with metals and metal ions	N/A	
830.6314	Oxidation/reduction: chemical incompatibility	49260303	Simple Science Limited	OWN	Volume 4
830.6315	Flammability	49260303	Simple Science Limited	OWN	Volume 4
830.6316	Explosibility		Product is not potentially explosive	N/A	
830.6317	Storage stability	49260304	Simple Science Limited	OWN	Volume 5
830.6319	Miscibility		Product is not an emulsifiable liquid and is not to be diluted with petroleum solvent	N/A	

Signature:

Name and Title: Seth DeGroot  
Project Manager

Date:  
Nov 26, 2013



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**Data Matrix**

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<b>Applicant's/Registrant's Name and Address:</b> Simple Science Limited 530 N 3 <sup>rd</sup> St, #310 Minneapolis, MN 55401	<b>Product Name:</b>  CleanSmart				
<b>Ingredients:</b> Hypochlorous acid (CAS# 7790-92-3)					
<b>Guideline Reference Number</b>	<b>Guideline Study Name</b>	<b>MRID Number</b>	<b>Submitter</b>	<b>Status</b>	<b>Notes</b>

830.6320	Corrosion characteristics	49260304	Simple Science Limited	OWN	Volume 5
830.6321	Dielectric breakdown voltage		Product is not to be used around electrical equipment	N/A	
830.7000	pH	49260303	Simple Science Limited	OWN	Volume 4
830.7100	Viscosity	49260303	Simple Science Limited	OWN	Volume 4
830.7300	Density/relative density/bulk density	49260303	Simple Science Limited	OWN	Volume 4
830.7520	Particle size, fiber length, and diameter distribution		Product is not a fibrous test substance	N/A	
<b>§ 158.2220: Product Performance Data Requirements</b>					
810.2200	<i>Staphylococcus aureus</i> (ATCC 6538)	49260305	Simple Science Limited	OWN	Volume 6
810.2200	<i>Salmonella enterica</i> (ATCC 10708)	49260306	Simple Science Limited	OWN	Volume 7
810.2200	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	49260307	Simple Science Limited	OWN	Volume 8
810.2200	<i>Streptococcus pyogenes</i> (ATCC 19615)	49260308	Simple Science Limited	OWN	Volume 9
810.2200	<i>Enterococcus faecalis</i> – VRE (ATCC 51575)	49260309	Simple Science Limited	OWN	Volume 10
810.2200	Methicillin Resistant <i>Staphylococcus aureus</i> (ATCC 33592)	49260310	Simple Science Limited	OWN	Volume 11
810.2200	<i>Listeria monocytogenes</i> (ATCC 19117)	49260311	Simple Science Limited	OWN	Volume 12
810.2200	Herpes Simplex Virus Type 1 (ATCC VR-733)	49260312	Simple Science Limited	OWN	Volume 13
810.2200	Herpes Simplex Virus Type 2 (ATCC VR-734)	49260313	Simple Science Limited	OWN	Volume 14
810.2200	Human Immunodeficiency Virus Type 1, Strain HTLV-IIIB	49260314	Simple Science Limited	OWN	Volume 15
810.2200	Influenza A H1N1 (ATCC VR-1469)	49260315	Simple Science Limited	OWN	Volume 16
810.2200	Rhinovirus Type 37 (ATCC VR-1147)	49260316	Simple Science Limited	OWN	Volume 17
810.2200	Human Coronavirus (ATCC VR-740)	49260317	Simple Science Limited	OWN	Volume 18
810.2200	Respiratory Syncytial Virus (ATCC VR-26)	49260318	Simple Science Limited	OWN	Volume 19

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<b>Ingredients:</b> Hypochlorous acid (CAS# 7790-92-3)		
<b>Guideline Reference Number</b>	<b>Guideline Study Name</b>	<b>MRID Number</b>
		<b>Submitter</b>
		<b>Status</b>
		<b>Notes</b>

810.2200	<i>Trichophyton mentagrophytes</i> (ATCC 9533)	49260319	Simple Science Limited	OWN	Volume 20
810.2200	<i>Escherichia coli</i> (ATCC 11229)	49260320	Simple Science Limited	OWN	Volume 21
	<b>Non-food Contact:</b>				
810.2300	<i>Staphylococcus aureus</i> (ATCC 6538)	49260321	Simple Science Limited	OWN	Volume 22
810.2300	<i>Enterobacter aerogenes</i> (ATCC 13048)	49260322	Simple Science Limited	OWN	Volume 23
810.2300	<i>Streptococcus pneumoniae</i> (ATCC 6305)	49260323	Simple Science Limited	OWN	Volume 24
810.2300	<i>Salmonella enterica</i> (ATCC 10708)	49260324	Simple Science Limited	OWN	Volume 25
810.2300	Methicillin Resistant <i>Staphylococcus aureus</i> (ATCC 33592)	49260325	Simple Science Limited	OWN	Volume 26
810.2300	<i>Enterococcus faecalis</i> - VRE (ATCC 51575)	49260326	Simple Science Limited	OWN	Volume 27
810.2300	<i>Escherichia coli</i> (ATCC 11229)	49260327	Simple Science Limited	OWN	Volume 28
	<b>Food Contact:</b>				
810.2300	<i>Staphylococcus aureus</i> (ATCC 6538)	49260328	Simple Science Limited	OWN	Volume 29
810.2300	<i>Salmonella enterica</i> serovar Typhi (ATCC 6539)	49260329	Simple Science Limited	OWN	Volume 30
810.2300	<i>Escherichia coli</i> (ATCC 11229)	49260330	Simple Science Limited	OWN	Volume 31
<b>§ 158.2230: Toxicology Data Requirements</b>					
870.1100	Acute oral toxicity	46232405	Occulus Innovative Sciences Inc.	PAY	
870.1200	Acute dermal toxicity	46232406	Occulus Innovative Sciences Inc.	PAY	
870.1300	Acute inhalation toxicity	46232407	Occulus Innovative Sciences Inc.	PAY	
870.2400	Primary eye irritation	46453701	Occulus Innovative Sciences Inc.	PAY	
870.2500	Primary dermal irritation	46453702	Occulus Innovative Sciences Inc.	PAY	
870.2600	Dermal sensitization	46232410	Occulus Innovative Sciences Inc.	PAY	

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<b>Ingredients:</b> Hypochlorous acid (CAS# 7790-92-3)					
<b>Guideline Reference Number</b>	<b>Guideline Study Name</b>	<b>MRID Number</b>	<b>Submitter</b>	<b>Status</b>	<b>Notes</b>

Simple Science Limited	OWN	Volume 2
Simple Science Limited	OWN	Volume 2
Simple Science Limited	OWN	Volume 2
Simple Science Limited	OWN	Volume 2
Simple Science Limited	OWN	Volume 2
Simple Science Limited	OWN	Volume 3
Simple Science Limited	OWN	Volume 2
Simple Science Limited	OWN	Volume 2
Simple Science Limited	OWN	Volume 2
Simple Science Limited	OWN	Volume 2
Simple Science Limited	OWN	Volume 4
Simple Science Limited	OWN	Volume 4
Simple Science Limited	OWN	Volume 4
Not expected to come into contact with metals and metal ions	N/A	
Simple Science Limited	OWN	Volume 4
Simple Science Limited	OWN	Volume 4
Product is not potentially explosive	N/A	
Simple Science Limited	OWN	Volume 5
Product is not an emulsifiable liquid and is not to be diluted with petroleum solvent	N/A	

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<b>Guideline Reference Number</b>	<b>Guideline Study Name</b>	<b>MRID Number</b>	<b>Submitter</b>	<b>Status</b>	<b>Notes</b>

	Simple Science Limited	OWN	Volume 5
	Product is not to be used around electrical equipment	N/A	
	Simple Science Limited	OWN	Volume 4
	Simple Science Limited	OWN	Volume 4
	Simple Science Limited	OWN	Volume 4
	Product is not a fibrous test substance	N/A	
	Simple Science Limited	OWN	Volume 6
	Simple Science Limited	OWN	Volume 7
	Simple Science Limited	OWN	Volume 8
	Simple Science Limited	OWN	Volume 9
	Simple Science Limited	OWN	Volume 10
	Simple Science Limited	OWN	Volume 11
	Simple Science Limited	OWN	Volume 12
	Simple Science Limited	OWN	Volume 13
	Simple Science Limited	OWN	Volume 14
	Simple Science Limited	OWN	Volume 15
	Simple Science Limited	OWN	Volume 16
	Simple Science Limited	OWN	Volume 17
	Simple Science Limited	OWN	Volume 18

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	Simple Science Limited	OWN	Volume 19
	Simple Science Limited	OWN	Volume 20
	Simple Science Limited	OWN	Volume 21
	Simple Science Limited	OWN	Volume 22
	Simple Science Limited	OWN	Volume 23
	Simple Science Limited	OWN	Volume 24
	Simple Science Limited	OWN	Volume 25
	Simple Science Limited	OWN	Volume 26
	Simple Science Limited	OWN	Volume 27
	Simple Science Limited	OWN	Volume 28
	Simple Science Limited	OWN	Volume 29
	Simple Science Limited	OWN	Volume 30
	Simple Science Limited	OWN	Volume 31
	Occulus Innovative Sciences Inc.	PAY	
	Occulus Innovative Sciences Inc.	PAY	
	Occulus Innovative Sciences Inc.	PAY	
	Occulus Innovative Sciences Inc.	PAY	
	Occulus Innovative Sciences Inc.	PAY	
	Occulus Innovative Sciences Inc.	PAY	

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